Всемирная
организация здравоохранения

СЕМЬДЕСЯТ ВТОРАЯ СЕССИЯ
ВСЕМИРНОЙ АССАМБЛЕИ ЗДРАВООХРАНЕНИЯ
Пункт 12.6 предварительной повестки дня

WHA72/28
4 апреля 2019 г.

Ликвидация оспы: уничтожение запасов вируса натуральной оспы

Доклад Генерального директора

1. В резолюции WHA60.1 (2007 г.) «Ликвидация оспы: уничтожение запасов вируса натуральной оспы» шестидесятая сессия Всемирной ассамблеи здравоохранения поручила Генеральному директору подготовить в 2010 г. широкий обзор результатов проведенных и проводимых в настоящее время исследований, а также планов проведения будущих необходимых исследований для целей глобального общественного здравоохранения для их обсуждения на шестьдесят четвертой сессии Всемирной ассамблеи здравоохранения в 2011 году.

2. В своем решении WHA64(11) (2011 г.), принятом по результатам выполненного обзора исследований оспы, шестьдесят четвертая сессия Всемирной ассамблеи здравоохранения подтвердила принятые ею ранее резолюции (WHA49.10 (1996 г.) и WHA52.10 (1999 г.)) о том, что остающиеся запасы вируса натуральной оспы должны быть уничтожены. Она также подтвердила необходимость достижения консенсуса в отношении предлагаемой даты уничтожения запасов вируса натуральной оспы, когда результаты научных исследований, имеющие решающее значение для совершенствования мер общественного здравоохранения, которые могут быть приняты в случае вспышки заболевания, позволят это сделать.

3. На шестьдесят девятой сессии Всемирной ассамблеи здравоохранения в мае 2016 г. государства-члены обсудили сроки уничтожения существующих запасов вируса натуральной оспы. Учитывая появление технологий синтетической биологии, позволяющих создать вирус натуральной оспы с использованием общедоступной информации и обычных лабораторных методов, Ассамблея здравоохранения настоятельно призвала Консультативный комитет по исследованию вируса натуральной оспы проанализировать существующие потребности в исследованиях с использованием живого вируса натуральной оспы. Ассамблея здравоохранения постановила, что семьдесят вторая сессия Всемирной ассамблеи здравоохранения в 2019 г. обсудит вопрос об уничтожении запасов вируса натуральной оспы в качестве одного из существенных пунктов повестки дня. Ассамблее здравоохранения представлялись и принимались ею к сведению ежегодные промежуточные доклады о статусе исследований.

4. В настоящем докладе представлен обзор работы, проделанной Секретариатом в порядке подготовки к семьдесят второй сессии Всемирной ассамблеи здравоохранения.

В нем резюмируются ход работы и решения двадцатого совещания Консультативного комитета ВОЗ по исследованию вируса натуральной оспы (состоявшегося в Женеве 26-27 сентября 2018 г.)[1] и содержится обновленная информация о проводимых раз в два года инспекционных проверках обеспечения биобезопасности в двух разрешенных местах хранения запасов вируса натуральной оспы, которыми являются Сотрудничающий центр ВОЗ по диагностике ортопоксвирусных инфекций и музей штаммов и ДНК вируса оспы при Государственном научном центре вирусологии и биотехнологии («Вектор»), поселок Кольцово, Новосибирская область, Российская Федерация, и Сотрудничающий центр ВОЗ по изучению вируса натуральной оспы и других поксвирусных инфекций, Центры контроля и профилактики заболеваний (ЦКПЗ), Атланта, штат Джорджия, Соединенные Штаты Америки.

ДЕЙСТВИЯ СЕКРЕТАРИАТА

Инспекционные проверки обеспечения биобезопасности в местах хранения вируса натуральной оспы

5. Каждые два года инспекционные группы ВОЗ по проверке биобезопасности посещают места хранения вируса натуральной оспы в Российской Федерации и Соединенных Штатах Америки и проверяют помещения биоизоляции[2]. В ходе нынешнего раунда проводимых раз в два года инспекционных проверок обеспечения биобезопасности в местах хранения вируса инспекционная группа посетила центр «Вектор» в период с 28 января по 2 февраля 2019 г. и планирует посетить ЦКПЗ в период с 20 по 24 мая 2019 г.; обе инспекционные проверки проведет одна и та же международная группа экспертов в области биобезопасности, действующая под руководством ВОЗ. Протокол проведения инспекционных проверок соответствует Стандарту управления лабораторными биорисками CWA15793 Европейского комитета по стандартизации, который охватывает 16 элементов управления лабораторными биорисками. Доклады об обеих инспекционных проверках будут опубликованы на веб-сайте ВОЗ.

6. В результате проведения инспекционных проверок биобезопасности в обоих местах хранения вируса было установлено, что оба они соответствуют международным стандартам биобезопасности и биозащиты, было сделано заключение о том, что безопасное хранение запасов вируса натуральной оспы обеспечено, и были вынесены рекомендации относительно постоянного повышения биобезопасности в соответствии с развивающимися знаниями и передовой практикой.

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[1] Доклад двадцатого совещания Консультативного комитета по исследованию вируса натуральной оспы (http://www.who.int/csr/resources/publications/smallpox/variola-research-november-2018/en/, в процессе подготовки).

[2] Доклады о двух предыдущих инспекционных проверках (в 2016 и 2017 гг.) см. по ссылкам: https://apps.who.int/iris/bitstream/handle/10665/272366/WHO-WHE-CPI-2018.14-eng.pdf и http://apps.who.int/iris/bitstream/handle/10665/272367/WHO-WHE-CPI-2018.15-eng.pdf?ua=, по состоянию на 22 февраля 2019 г.).

Обзор исследований вируса натуральной оспы

7. На своем двадцатом совещании (Женева, 26-27 сентября 2018 г.) Консультативный комитет по исследованию вируса натуральной оспы отметил, что работа с вирусом натуральной оспы в рамках утвержденной программы исследований велась под его контролем. В 2018 г. Консультативный комитет оценил, а Секретариат ВОЗ одобрил 10 текущих предложений по проектам.

8. На своем совещании Консультативный комитет рассмотрел доклады Секретариата о проведенной за год работе и доклады двух сотрудничающих центров о коллекциях вируса, находящихся у них на хранении. Консультативный комитет оценил работу каждого из центров и фармацевтических компаний, сотрудничающих в рамках разрешенной программы исследований с целью разработки диагностических тестов, противооспенных вакцин, а также антивирусных и терапевтических агентов. Консультативному комитету были также представлены доклады о состоянии Чрезвычайного запаса противооспенных вакцин ВОЗ.

9. Консультативный комитет тщательно проанализировал как результаты текущих исследований, так и целесообразность дальнейших исследований с использованием живого вируса натуральной оспы. Было особо отмечено то, что в июле 2018 г. Управление по контролю качества пищевых продуктов и лекарственных препаратов Соединенных Штатов выдало разрешение на применение противовирусного агента тековиримат для лечения оспы, признав его соответствующим всем нормативным требованиям. Тековиримат – первый лекарственный препарат, разрешенный к применению против вируса оспы. Консультативный комитет отметил постоянный прогресс в разработке других противовирусных препаратов, таких как бринцидофовир и NIOCH-14, доклинические и клинические исследования которых находятся в продвинутых стадиях, и моноклональных антител, нейтрализующих вирус натуральной оспы более эффективно, чем иммунноглобулин против вируса осповакцины.

10. Консультативный комитет отметил результаты успешного исследования не меньшей эффективности вакцины третьего поколения с лучшей переносимостью, чем у существующих вакцин, и прогресс, достигнутый в процессе разработки более иммунногенной и менее реактогенной вакцины четвертого поколения с улучшенным профилем безопасности. Он также отметил успехи в получении новых методов и средств диагностики: в центре «Вектор» были разработаны новая мультиплексная полимеразная цепная реакция (ПЦР) в реальном времени для видоспецифической идентификации патогенных для человека ортопоксвирусов и новый набор реагентов, а в ЦКПЗ – диагностические тесты для мультиплексного анализа на ортопоксвирусы, в том числе вирус натуральной оспы, для использования в автоматизированных диагностических платформах с применением готовых наборов реагентов, основанный на белках метод обнаружения вируса натуральной оспы с использованием моноклональных антител, пригодный к применению в отдаленных районах, а также метод микроматричного анализа вируса натуральной оспы с применением белкового микрочипа для оценки реакции антител.

11. Консультативный комитет отметил пользу исследований вируса натуральной оспы, в том числе возможности применения результатов этих исследований для борьбы со вспышками оспы обезьян, которые в настоящее время вновь участились в Центральной и Западной Африке. Консультативный комитет приветствовал возможность проанализировать вопрос о целесообразности исследований с использованием вируса натуральной оспы в интересах профилактики и контроля за распространением других ортопоксвирусов и вновь подчеркнул важность обеспечения готовности к вспышкам оспы в отдельных странах и на глобальном уровне и, в частности, наличия и доступности средств диагностики и других соответствующих инструментов.

12. Членам Консультативного комитета было предложено рассмотреть вопрос о том, является ли живой вирус натуральной оспы необходимым для дальнейших фундаментальных исследований в области диагностики, разработки вакцин и противовирусных препаратов, применяемых против оспы, в интересах охраны здоровья населения.

13. Большинство членов Консультативного комитета пришли к мнению об отсутствии необходимости сохранения живого вируса натуральной оспы для разработки вакцин, кроме запасов вируса, которые используются для уже утвержденных исследований. Что касается вопроса о дальнейшем использовании живого вируса натуральной оспы для получения новых методов диагностики, необходимых в интересах охраны здоровья населения, мнения членов Консультативного комитета разошлись.

14. Большинство членов Консультативного комитета выразили мнение, что живой вирус натуральной оспы все еще необходим для разработки новых противовирусных препаратов от оспы. Было особо отмечено, что оказание содействия разработке и лицензированию второго противовирусного препарата, который по своему механизму действия отличался бы от тековиримата – вещества, разрешенного к применению в 2018 г., было бы рациональным и важным шагом.

Риск возвращения оспы в свете появления технологий синтетической биологии

15. Члены Консультативного комитета напомнили о сделанном в 2015 г. заключении Независимой консультативной группы по последствиям для общественного здравоохранения использования технологий синтетической биологии в отношении оспы[1], согласно которому риск возвращения оспы повысился, и характер этого риска продолжает меняться. Они отметили, что эта проблема вышла на первый план после того, как был проведен синтез de novo вируса оспы лошадей, о чем Консультативный

[1] The Independent Advisory Group on Public Health Implications of Synthetic Biology Technology Related to Smallpox: meeting report. Geneva: World Health Organization; 2015 (https://www.who.int/csr/resources/publications/smallpox/synthetic-biology-technology-smallpox/en/, по состоянию на 22 февраля 2019 г.).

комитет сообщил на своей восемнадцатой сессии[1] в 2016 г., а соответствующий научный доклад был опубликован в рецензируемом журнале в январе 2018 года.

16. Передача образцов ДНК вируса натуральной оспы, обращение с ними и их синтез осуществляются в соответствии с рядом рекомендаций, изначально принятых Специальным комитетом по ортопоксвирусным инфекциям, а затем актуализированных Консультативным комитетом по исследованию вируса натуральной оспы. Независимая консультативная группа по последствиям для общественного здравоохранения технологии синтетической биологии, связанной с оспой, рекомендовала пересмотреть правила ВОЗ, касающиеся обращения с вирусом натуральной оспы, с целью минимизировать риск чрезвычайного происшествия в лабораторных условиях при использовании технологии синтетической биологии. Поэтому в январе 2016 г. прежние рекомендации были актуализированы с учетом новых реалий, связанных с возможностями синтетической биологии[2]. На шестьдесят девятой сессии Всемирной ассамблеи здравоохранения, состоявшейся в мае 2016 г.[3], государства-члены приняли к сведению доклад Секретариата и с удовлетворением отметили пересмотр рекомендаций ВОЗ, касающихся синтеза и использования ДНК вируса натуральной оспы. Как было отмечено в методическом документе, данные рекомендации предназначены для включения в руководства по обеспечению биобезопасности и соответствующее законодательство отдельных государств-членов.

17. На двадцатом совещании Консультативного комитета ВОЗ по исследованию вируса натуральной оспы его члены напомнили о пересмотренных в 2016 г. актуализированных рекомендациях ВОЗ в отношении передачи образцов ДНК вируса натуральной оспы, обращения с ними и их синтеза. Данные рекомендации гласят, что генная инженерия вируса натуральной оспы и попытки изготовить живой вирус из ДНК категорически запрещены, в них особо подчеркивается, что любые исследования с использованием живого вируса натуральной оспы должны проводиться в лабораториях с максимальным уровнем биозащиты в одном из двух учреждений, являющихся глобальными местами хранения вируса, и только с предварительного разрешения ВОЗ, и в них указано, что ни одна лаборатория, кроме сотрудничающих центров ВОЗ, в которых осуществляется хранение вируса натуральной оспы, не может хранить ДНК вируса натуральной оспы, составляющую более 20% от полного генома. Тем не менее, Консультативный комитет признал необходимость постоянной работы по обеспечению готовности к принятию мер в отношении потенциальных последствий синтеза и возможного возвращения вируса натуральной оспы.

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[1] Advisory Committee on Variola Virus Research, 18th meeting (https://www.who.int/csr/resources/publications/smallpox/18-ACVVR-Final.pdf?ua=1, по состоянию на 4 марта 2019 г.).

[2] Данные пересмотренные рекомендации резюмированы в документе «WHO Recommendations concerning the distribution, handling and synthesis of variola virus DNA. 2016» (https://www.who.int/csr/disease/smallpox/handling-synthesis-variola-DNA.pdf?ua=1, по состоянию на 14 марта 2019 г.).

[3] См. документы A69/23 (http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_23-en.pdf) и A69/2016/REC/3 (http://apps.who.int/gb/ebwha/pdf_files/WHA69-REC3/A69_2016_REC3-en.pdf#page=1), оба по состоянию на 14 марта 2019 г.).

Порядок использования Чрезвычайного запаса противооспенных вакцин ВОЗ

18. В ноябре 2013 г. Стратегическая консультативная группа экспертов ВОЗ по иммунизации представила рекомендации в отношении порядка иммунизации от оспы и соображения относительно запаса вакцин[1]. Чрезвычайный запас противооспенных вакцин ВОЗ состоит из хранящегося в Швейцарии под контролем Секретариата физического запаса объемом 2,8 миллиона доз, инвентаризация которого была завершена в июле 2018 г., и зарезервированного запаса объемом 27 миллионов доз, который хранится в следующих государствах-членах: Франции, Германии, Новой Зеландии и Соединенных Штатах Америки. Соединенное Королевство Великобритании и Северной Ирландии предоставило финансовые средства на цели закупки вакцин для физического запаса ВОЗ. Этот запас состоит из вакцины против оспы первого поколения (полученной из разных источников и использовавшейся в последние годы реализации программы ликвидации оспы) и лицензированной вакцины второго поколения (ACAM2000). Активность вакцин, находящихся как в физическом, так и в зарезервированном запасе, регулярно проверяется.

19. В декабре 2017 г. был опубликован порядок использования Чрезвычайного запаса противооспенных вакцин ВОЗ в случае события, связанного с оспой[2]. В этом документе изложен порядок выдачи странам вакцины против оспы (в том числе разбавителей) и вспомогательных средств (бифуркационных игл и шприцов для разведения вакцины) из Чрезвычайного запаса, юридические положения, касающиеся выдачи вакцин, требования материально-технического обеспечения, форма запроса на предоставление вакцины, а также правила и условия предоставления вакцины странам. Секретариат планирует провести имитационные учения, для того чтобы протестировать процедуры использования противооспенных вакцин в чрезвычайной ситуации. Порядок использования Чрезвычайного запаса противооспенных вакцин будет корректироваться по мере совершенствования методов и средств обеспечения готовности и планирования действий на основе научных достижений и наращивания потенциала для обеспечения безопасности здоровья населения мира.

20. Как рекомендовала Стратегическая консультативная группа экспертов по иммунизации, в случае события, связанного с оспой, вакцинации должны подлежать только лица, имевшие контакт с носителями заболевания, сотрудники медицинских служб оперативного реагирования, имеющие прямой или косвенный контакт с симптоматичными пациентами или их биологическими жидкостями, а также сотрудники лабораторий, которые могут иметь прямой контакт с пробами во время их отбора, подготовки и обработки. Учитывая, что объем запасов противооспенной вакцины во

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[1] Meeting of the Strategic Advisory Group of Experts on immunization – conclusion and recommendations. 2013 and (https://www.who.int/wer/2014/wer8901.pdf?ua=1 and. for a summary of the meeting. http://www.who.int/immunization/sage/report_summary_november_2013/en/index.html. по состоянию на 22 февраля 2019 г).

[2] Operational framework for the deployment of the World Health Organization Smallpox Vaccine Emergency Stockpile in response to a smallpox event. Geneva: World Health Organization; 2017 (http://apps.who.int/iris/bitstream/handle/10665/259574/9789241513418-eng.pdf?sequence=1, по состоянию на 22 февраля 2019 г.).

всем мире составляет порядка 600-700 миллионов доз и что объем ее производства может быть увеличен, существующий объем запасов ВОЗ, в том числе зарезервированных, может считаться достаточным для принятия необходимых мер в случае вспышки заболевания. Как рекомендовала Стратегическая консультативная группа экспертов по иммунизации, в настоящее время профилактической вакцинации от оспы должны подлежать только сотрудники лабораторий, работающие с ортопоксвирусами.

21. В ноябре 2018 г. ВОЗ опубликовала документ под названием "Identifying and responding to serious adverse events following immunization following use of smallpox vaccine during a public health emergency" (Выявление и принятие мер в отношении серьезных неблагоприятных проявлений после иммунизации в результате использования противооспенной вакцины в условиях чрезвычайной ситуации в области общественного здравоохранения)[1]. Этот документ содержит рекомендации относительно оперативного внедрения механизмов контроля за безопасным применением вакцин в странах, в которых используются противооспенные вакцины в случае события, связанного с оспой, или вспышки оспы, адресованные национальным комитетам по реагированию на чрезвычайную или кризисную ситуацию, руководству национальных программ иммунизации, работникам здравоохранения, работникам служб иммунизации и другим категориям лиц, участвующим в реагировании на событие или вспышку заболевания.

УНИЧТОЖЕНИЕ ВИРУСА НАТУРАЛЬНОЙ ОСПЫ И ДНК ВИРУСА НАТУРАЛЬНОЙ ОСПЫ ГОСУДАРСТВАМИ-ЧЛЕНАМИ

22. В январе 2014 г. фрагменты ДНК клонированного вируса натуральной оспы, хранившиеся в Южной Африке, были уничтожены в присутствии специалистов ВОЗ по биобезопасности, члена Консультативного комитета по исследованию вируса натуральной оспы и других свидетелей в соответствии с обновленной процедурой сертификации, изложенной в докладе о состоявшемся в 1994 г. совещании Специального комитета по ортопоксвирусным инфекциям[2].

23. В июне 2014 г. в Соединенных Штатах Америки на одном из объектов были обнаружены хранившиеся там несколько десятилетий 16 флаконов, которые содержали лиофилизированный материал и либо имели маркировку «натуральная оспа», либо вызывали подозрение на наличие в них вируса натуральной оспы. После их безопасной доставки в разрешенное ВОЗ место хранения и анализа содержимого было установлено, что шесть образцов содержали ДНК вируса натуральной оспы, причем все они содержали жизнеспособный вирус. Полное геномное секвенирование образцов показало, что образцы содержали три известных и один ранее неизвестный штаммы натуральной оспы. По завершении лабораторного анализа, образцы были уничтожены в присутствии

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[1] Identifying and responding to serious adverse events following use of smallpox vaccine during a public health emergency: a guidance document for smallpox vaccine safety surveillance. Geneva: World Health Organization; 2018. Licence: CC BY-NC-SA 3.0 IGO (https://www.who.int/vaccine_safety/Smallpox_AEFI_guidance_doc/en/, по состоянию на 4 марта 2019 г.).

[2] Report of the meeting of the Ad Hoc Committee on Orthopoxivirus Infections. Geneva: Switzerland; 1994 (http://apps.who.int/iris/handle/10665/59062, по состоянию на 22 февраля 2019 г.).

специалистов ВОЗ по биобезопасности, члена Консультативного комитета по исследованию вируса натуральной оспы и других свидетелей.

ДЕЙСТВИЯ АССАМБЛЕИ ЗДРАВООХРАНЕНИЯ

24. Ассамблее здравоохранения предлагается принять настоящий доклад к сведению.

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世界衛生大會 決議
قرار جمعية الصحة العالمية
RESOLUTION OF THE WORLD HEALTH ASSEMBLY
RÉSOLUTION DE L'ASSEMBLÉE MONDIALE DE LA SANTÉ
РЕЗОЛЮЦИЯ ВСЕМИРНОЙ АССАМБЛЕИ ЗДРАВООХРАНЕНИЯ
RESOLUCION DE LA ASAMBLEA MUNDIAL DE LA SALUD

THIRTY-THIRD WORLD HEALTH ASSEMBLY

WHA33.4

14 May 1980

GLOBAL SMALLPOX ERADICATION

The Thirty-third World Health Assembly,

Having reviewed the report of the Global Commission for the Certification of Smallpox Eradication prepared in December 1979;

Mindful that smallpox was a most devastating disease, sweeping in epidemic form through many countries since earliest times, and leaving death, blindness and disfigurement in its wake; that despite the existence of a vaccine since the beginning of the last century, the disease had persisted in many parts of the world; and that only a decade ago the disease was rampant in Africa, Asia and South America;

Affirming that the commitment of the Health Assembly to the worldwide eradication of smallpox, first initiated, in accordance with resolution WHA11.54, in 1958, and intensified, in accordance with resolution WHA20.15, in 1967, has now been met;

Expressing appreciation of the efforts made by all nations to achieve global smallpox eradication, either through their national programmes or through the assistance which they provided, with the wholehearted support of multilateral, bilateral and voluntary agencies and with the constant encouragement of the world's news media;

1. ENDORSES the conclusions of the Global Commission that smallpox eradication has been achieved throughout the world, as proclaimed in resolution WHA33.3, and that there is no evidence that smallpox will return as an endemic disease;

2. FURTHER ENDORSES the recommendations of the Global Commission on the policy for the post-eradication era, annexed to this resolution;

3. REQUESTS Member States to cooperate fully in the implementation of the Commission's recommendations;

4. URGES, in particular, the immediate implementation of the recommendations on the discontinuation of smallpox vaccination except for investigators at special risk and the termination of the requirement for international certificates of vaccination against smallpox in Member States which have not already taken this measure; the continued epidemiological surveillance of suspected smallpox cases; the monitoring of safety measures in laboratories retaining variola virus and further reduction in the number of such laboratories; and the promotion of research on orthopoxviruses;

5. REQUESTS the Director-General to ensure the production, within a reasonable period of time, of appropriate publications describing smallpox and its eradication, in order to preserve the unique historical experience of eradication and thereby contribute to the development of other health programmes;

6. INVITES all Member States, as well as multilateral, bilateral and voluntary agencies, to ensure that the cooperation and support which has brought about the global eradication of smallpox is continued in other fields, and to invest the resources saved as a result of smallpox eradication in other priority health programmes, so as to maintain the struggle towards better health for all mankind;

7. CALLS ON the Director-General to promote and coordinate the implementation of the Global Commission's recommendations on policy for the post-eradication era, so that the world may remain permanently free of this disease and to report on this matter to future Health Assemblies as necessary.

ANNEX

RECOMMENDATIONS OF THE GLOBAL COMMISSION FOR THE CERTIFICATION OF SMALLPOX ERADICATION REGARDING POLICY FOR THE POST-ERADICATION ERA

Vaccination policy

Recommendation 1. Smallpox vaccination should be discontinued in every country except for investigators at special risk.

Recommendation 2. An international certificate of vaccination against smallpox should no longer be required of any traveller.

Reserve stocks of vaccine

Recommendation 3. Sufficient freeze-dried smallpox vaccine to vaccinate 200 million people should be maintained by WHO in refrigerated depots in two countries, together with stocks of bifurcated needles.

Recommendation 4. The stored vaccine should be periodically tested for potency.

Recommendation 5. Seed lots of vaccinia virus suitable for the preparation of smallpox vaccine should be maintained in designated WHO collaborating centres.

Recommendation 6. National health authorities that have vaccine stocks should be asked to inform WHO of the amount of vaccine maintained.

Investigation of suspected smallpox cases

Recommendation 7. In order to maintain public confidence in the fact of global eradication, it is important that rumours of suspected smallpox, which can be expected to occur in many countries, should be thoroughly investigated. Information should be provided to WHO, if requested, so that it can be made available to the world community.

Recommendation 8. WHO should maintain an effective system to coordinate and participate in the investigation of suspected smallpox cases throughout the world. The international smallpox-rumour register should be maintained.

Laboratories retaining variola virus stocks

Recommendation 9. No more than four WHO collaborating centres should be approved as suitable to hold, and handle, stocks of variola virus. A collaborating centre would be approved only if it had adequate containment facilities. Each such centre should provide WHO annually with relevant information on its safety measures and should be inspected periodically by WHO.

Recommendation 10. Other laboratories should be asked to destroy any stocks of variola virus that they hold, or transfer them to an approved WHO collaborating centre.

Human monkeypox

Recommendation 11. In collaboration with country health services WHO should organize and assist a special surveillance programme on human monkeypox, its epidemiology, and its ecology in areas where it is known to have occurred. The programme should continue until 1985, when a further assessment of the situation should be made.

Laboratory investigations

Recommendation 12. WHO should continue to encourage and coordinate research on orthopoxviruses.

Recommendation 13. WHO should maintain the system of WHO collaborating centres for carrying out diagnostic work and research on orthopoxviruses.

Recommendation 14. Research workers who do not work in a WHO collaborating centre and who wish to carry out experiments with variola or whitepox virus that are approved by the appropriate WHO committee should be offered the use of the special facilities in a WHO collaborating centre.

Recommendation 15. Research on poxviruses other than variola or whitepox viruses should not be performed under circumstances where there is any possibility of cross-contamination with these two agents.

Documentation of the smallpox eradication programme

Recommendation 16. WHO should ensure that appropriate publications are produced describing smallpox and its eradication and the principles and methods that are applicable to other programmes.

Recommendation 17. All relevant scientific, operational and administrative data should be catalogued and retained for archival purposes in WHO headquarters and perhaps also in several centres interested in the history of medicine.

WHO headquarters staff

Recommendation 18. An interregional team consisting of not less than two epidemiologists with past experience in the smallpox eradication campaign, plus supporting staff, should be maintained at WHO headquarters until at least the end of 1985. At least one additional field officer should be assigned to cover areas where human monkeypox is under investigation.

Recommendation 19. WHO should set up a committee on orthopoxvirus infections.

Eleventh Plenary Meeting, 14 May 1980
A33/VR/11

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世界衛生大會 決議 قرار جمعية الصحة العالميـــة
RESOLUTION OF THE WORLD HEALTH ASSEMBLY
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RESOLUCION DE LA ASAMBLEA MUNDIAL DE LA SALUD

FORTY-NINTH WORLD HEALTH ASSEMBLY **WHA49.10**

Agenda item 18.1 25 May 1996

Smallpox eradication - destruction of variola virus stocks

The Forty-ninth World Health Assembly,

Noting that on 8 May 1980 the Thirty-third World Health Assembly in resolution WHA33.3 declared the global eradication of smallpox;

Noting further that resolution WHA33.4 endorsed recommendations for the post-eradication era which specified that remaining stocks of variola virus should be held at only a limited number of sites, and that the stock of variola virus has since been reduced and restricted to the WHO collaborating centre on smallpox and other poxvirus infections designated at the Centers for Disease Control and Prevention, Atlanta, Georgia, USA, and the Russian State Research Centre of Virology and Biotechnology, Koltsovo, Novosibirsk Region, Russian Federation;

Recognizing that sequence information on the genome of several variola virus strains and the cloned DNA fragments of genome of variola virus allow scientific questions about the properties of the viral genes and proteins to be solved as well as any problem with diagnosis of suspected smallpox, and that the escape of variola virus from laboratories would be a serious risk as an increasing proportion of the population lack immunity to smallpox,

RECOMMENDS that the remaining stocks of variola virus, including all whitepox viruses, viral genomic DNA, clinical specimens and other material containing infectious variola virus, should be destroyed on 30 June 1999 after a decision has been taken by the Health Assembly, that being a moratorium of five-and-a-half years from the deadline of 31 December 1993 proposed by the ad hoc committee on orthopoxvirus infections, with a view to taking action to achieve a broader consensus.

Sixth plenary meeting, 25 May 1996
A49/VR/6

Функції лабораторії у системі епіднагляду

- Збір зразків
- Обробка зразків
- Транспортування зразків
- Реєстрація результатів (на папері та в електронному вигляді)
- Звітування про результати до:
  - особи, що їх направляла
  - До органів охорони здоров'я
- Аналіз зразків виділення/ідентифікації

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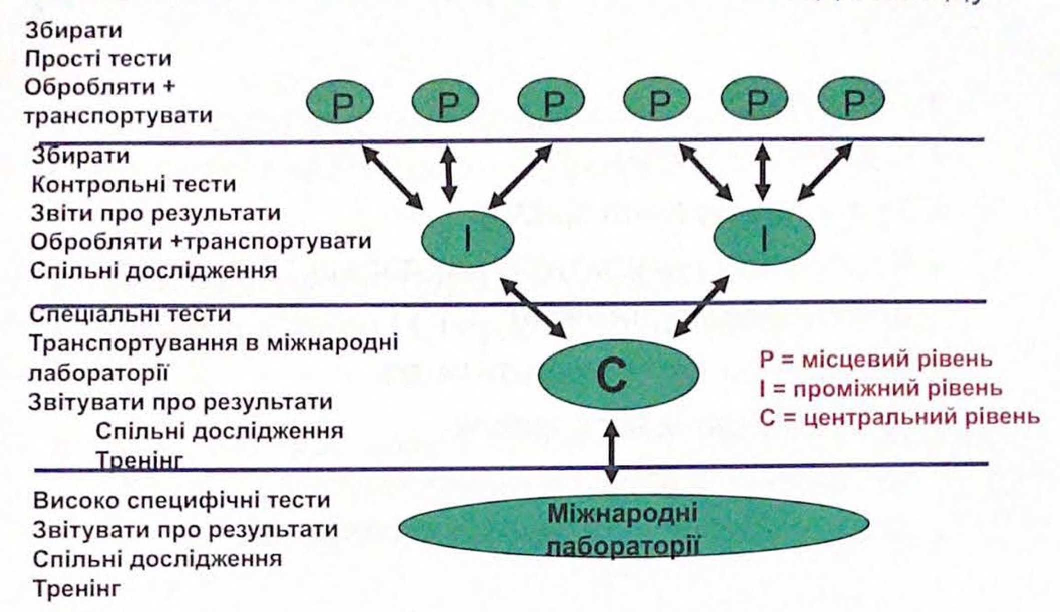
Лабораторні послуги корисні на всіх фазах реагування на хворобу

- Виявлення і підтвердження епідемії
- Епіднагляд за ендемічними хворобами (туберкульоз, малярія)
- Усунення та ліквідація хвороби

ТАКОЖ

- Виявлення нових збудників
- Епіднагляд за антимікробною резистентністю

Робочий процес лабораторії у системі епіднагляду



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"Якісна система епіднагляду не обов'язково гарантує прийняття правильних рішень, але вона зменшує шанси для прийняття неправильних."

Алекс Лангмур, 1963р.

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Література

- *Огляд системи епіднагляду* – презентація підготовлена Річардом С.Дікером, 2005 р.
- *Принципи та інструкції епіднагляду охорони здоров'я*, Стівен М.Теущ. Р. Еліот Чечіл
- *Сучасний курс оцінки систем епіднагляду охорони здоров'я*, MMWR, 27 червня 2001р.

ДОДАТКОВІ СЛАЙДИ

Синдромний та "вибірковий" епіднагляд

- *Синдромний епіднагляд* – зосереджується на одному чи сукупності симптомів більше, ніж на хворобі з встановленим діагнозом
- *"Вибірковий" епіднагляд* – короткочасний епіднагляд у порівнянні з постійним, як правило, до, протягом та після випадку із синдромом. Такий епіднагляд шукає умови, що пов'язані з біотероризмом

Синдроми, епіднагляд за синдромами після 11 вересня, Нью-Йорк

- Вдихання диму чи пилу
- Загострення стану дихальних шляхів
- Реакція збудженості
- Діарея / гастроентерит
- Інфекція верхніх та нижніх дихальних шляхів з гарячкою
- Сепсис або не травматичний шок
- Висип з гарячкою
- Менінгіт, енцефаліт, енцефалопатія
- Синдром схожий на ботулізм
- Непояснена смерть з анамнезом гарячки

Рекомендації по проекту

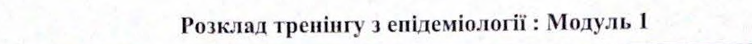
Епідеміологія – Модуль 1

Нижче представлений перелік рекомендацій, які можна використати при аналізі даних з епіднагляду за інфекційними захворюваннями. Ці кроки є тільки рекомендаціями, але Ви повинні побудувати графічне представлення даних на основі цих мінімальних вимог. Якщо у Вас з'являться запитання, запитуйте, будь ласка, у керівника секції. Будь- ласка, не забудьте підписати всі таблиці, діаграми та схеми.

Крок 1:	Виберіть 2 чи 3 захворювання на одну команду (такі команди можуть бути створені організацією або іншими групами).
Крок 2:	Отримайте дані епіднагляду за інфекційними захворюваннями у районному та національному масштабі за минулий рік. Якщо можливо, спробуйте отримати дані по групам населення щодо віку та статі людей.
Крок 3	Складіть таблицю захворюваності. Таблиця захворюваності з одним показником (вікові групи на національному рівні) Таблиця захворюваності з двома показниками (вікові групи та район)
Крок 4	Складіть лінійну діаграму на основі даних із вище складених таблиць. Покажіть захворюваність за рік, користуючись лінійною діаграмою
Крок 5	Складіть стовпчикову діаграму Захворюваність в межах району за рік (по місяцях) Захворюваність за віковими групами в межах 3 районів за один рік

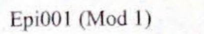
	Захворюваність за віковими групами в межах 3 районів за 5 років Стовпчикова діаграма поширення захворюваності за віковими групами за 5 років (у відсотках)
Крок 6:	Порівняйте показники захворюваності (Вам будуть потрібні дані епіднагляду та дані захворюваності по групах населення) Захворюваність за рік для Азербайджану Захворюваність за рік для певних районів Складіть діаграму показників представлених у попередніх 2 параграфах
Крок 7:	Напишіть коротке обгрунтування результатів, отриманих на основі Ваших таблиць, схем та діаграм





Розклад тренінгу з епідеміології : Модуль 1

Час	Понеділок	Вівторок	Середа	Четвер	П'ятниця
9:30-10:00		Клінічне розпізнавання – Віспа	Показники центральної локалізації	Вступ до системи епіднагляду за інфекційними захворюваннями – частина перша	Бруцельоз Епідеміологія та клініка захворювання #1 (продовження)
10:00-10:30	Знайомство та привітання	Вступ до статистики			
10:30-11:00	Вступ до ВРЧЗ				
11:00-11:30	**Перерва**	**Перерва**	**Перерва**	**Перерва**	**Перерва**
	Попереднє тестування	Вступ до статистики (практичне заняття)	Показники центральної локалізації(практичне заняття)	Вступ до системи епіднагляду за інфекційними захворюваннями – частина друга	Підсумкове тестування
11:30-12:00	Вступ до епідеміології				
12:00-12:30		Клінічне розпізнавання – Кліщовий енцефаліт	Показники поширення захворювань	Вступ до системи епіднагляду за інфекційними захворюваннями (практичне заняття)	Проект аналізу даних
12:30-13:00					Прощання
13:00-13:30	**Обід**	**Обід**	**Обід**	**Обід**	
13:30-14:00	Основні епідеміологічні поняття	Вступ до графічного представлення даних інфекційної захворюваності	Показники поширення захворювань (практичне заняття)	Бруцельоз Епідеміологія та клініка захворювання #1	
14:00-14:30	Визначення випадків інфекційних захворювань		Клінічне розпізнавання- Сибірка		
14:30-15:00					
	Перерва	**Перерва**	**Перерва**	**Перерва**	
15:00-15:30	Визначення випадків інфекційного захворювання (практичне заняття)	Вступ до графічного представлення даних інфекційної захворюваності (практичне заняття)	Клінічне розпізнавання - Бруцельоз	Бруцельоз Епідеміологія та клініка захворювання #1 (продовження)	
15:30-16:00					



Практикум з епідеміології

Модуль 1

Попереднє тестування

1. Інкубаційний період інфекційного захворювання визначається як період часу між:

- **Моментом зараження та появою перших симптомів (ознак)**
- **Появою клінічних ознак (симптомів) та початком захворювання**
- **Зараження та початком заразного періоду**
- **Початком заразного періоду та початком захворювання**

2. Захворюваність, яка виникає серед населення і перевищує звичайні масштаби або поширюється на всі країни класифікується як:

- **Спорадична**
- **Ендемічна**
- **Пандемічна**
- **Епідемічна**

3. Діаграма, в якій ширина стовпчиків вказує на різні класи, а їх висота на відносну частоту, називається:

- **Секторна діаграма**
- **Частотний багатокутник**
- **Гістограма**

4. Описова епідеміологія дає відповіді на наступні запитання (виберіть одне чи більше):

- **Хто**
- **Чому**
- **Коли**
- **Де**

5. Аналітична епідеміологія дає відповіді на наступне запитання:

- **Хто**
- **Чому**
- **Коли**
- **Де**

6. Епіднагляд за перебігом захворювання повинен включати:

- Збір даних
- Аналіз даних
- Дані про поширення захворювання
- Усе вищезгадане

7. Епідеміологи зацікавлені у вивченні:

- **Причини та умови виникнення захворювання і протиепідемічні заходи.**
- **Частота та територіальне поширення захворювання**
- **Причини взаємозв'язку між захворюваннями**
- **Усе вищезгадане**

8. У селі з населенням 1000 осіб було сімейне свято. Його відвідало 200 осіб. Із них: 100 - були жіночої статі, 20 – чоловічої статі та 80 – діти; через три дні у 100 осіб із 200 був поставлений діагноз сальмонельоз. Співвідношення кількості жінок до чоловіків на святі склало:

- **0,5**
- **5,0**
- **1,0**
- **Неможливо вирахувати, виходячи з наявних даних**

9. Див. запитання 8. Який відсоток людей, що відвідали свято, склали діти:

- **40%**
- **8%**
- **0,4%**
- **Неможливо вирахувати, виходячи з наявних даних**

10. Див. запитання 8. Співвідношення захворюваності при епідспалаху складає

- **0,1**
- **0,2**
- **0,5**
- Неможливо вирахувати, виходячи з наявних даних

11. Що з нижчеприведенного не є виміром дисперсії:

- **інтерквартильна проміжок**
- **середнє квадратичне відхилення**
- **стандартне відхилення**
- **медіана**

12. Використовуючи приведені нижче дані, визначте ряд значень з найменш стандартним відхиленням:

- 7, 9, 9, 10, 11, 12, 14, 17, 20, 90
- 7, 9, 9, 10, 11, 12, 14, 17, 17, 17
- 9, 9, 9, 10, 10, 10, 10, 10, 11, 11
- 9, 9, 9, 9, 9, 9, 9, 9, 9, 9

13. Стандартне відхилення вираховується наступним методом:

- **Сума груп значень поділена на кількість показників**
- **Квадратний корінь розбіжності**
- **Сума показників, що виходять за межі звичайного (найменше і найбільше значення) поділена на 2**
- **Нічого з вищенаведеного**

14. Термін "захворюваність " відноситься до нових випадків захворювання серед населення групи ризику за певний період часу, а термін "поширеність" випадків захворювання відноситься до пропорції між населенням та захворюванням у будь-який період часу:

- **Вірно**
- **Невірно**

15. Якісні показники включають наступні дані, крім:

- Дискретні дані
- Номінальні дані
- Постійні дані

16. Обчислити середнє арифметичне, медіану, моду та середнє квадратичне відхилення на основі наступних даних: 5, 10, 15, 20, 25, 30, 35, 40, 10, 10

- Відповідь (середнє арифметичне) ________
- Відповідь (медіана) _______

- Відповідь (мода) ____
- Відповідь (*середнє квадратичне відхилення*) ________

17. Епідеміологічний термін "Патогенність" означає:

- **Властивість збудника викликати захворювання.**
- **Здатність сприйнятливого організму інфікуватися від джерела.**

- **Важкість захворювання залежить від сприйнятливості організму.**

18. Які з наведених нижче показників відносяться до якісних:

- **Зріст**
- **Стать**
- **Кількість надходжень**
- **Артеріальний тиск**

19. Державна система епіднагляду – це постійний систематичний збір, аналіз, обробка та поширення даних про стан здоров'я. Коротко опишіть різницю між двома наступними термінами: активний та пасивний епіднагляд.
Порівняти активний епіднагляд з пасивним:

20. Порівняти чутливе визначення випадку інфекційного захворювання із специфічним визначенням:



Всесвітня організація охорони здоров'я

Fact sheet N°286
Revised March 2006

Кір

Кір залишається основною причиною смерті серед дітей молодшого віку, незважаючи на те, що уже протягом останніх 40 років існує безпечна та ефективна вакцина проти кору. 454 000 людей, більшість із них діти, померли від кору в 2004 році (це останній рік, за який представлені дані).

Кір – одна з найвідоміших контагіозних хвороб. Майже всі не імунізовані діти хворіють на кір, якщо заражаються вірусом. Кір – це гостра вірусна хвороба, що спричиняється вірусом із родини параміксовірусів. При захворюванні дихальних шляхів, вірус кору, як правило, росте в клітинах, що покривають задню стінку горла, та в клітинах, що вкривають легені. Кір – це хвороба людини, і випадки захворювання серед тварин невідомі.

Ознаки та симптоми

Першою ознакою інфекції, як правило, є підвищення температури тіла, що починається на 10-12 день після зараження та триває від одного до семи днів. На початковій стадії хвороби у пацієнта з'являється нежить, кашель, почервоніння і сльози з очей, білі плями на внутрішній стороні щік. Через декілька днів з'являється висип. Висип поширюється вниз, охоплюючи руки та ноги. Висип триває від п'яти до шести днів, потім зникає. Висип з'являється, в

середньому, на 14 день після зараження вірусом, але може з'являтися від 7 до 18 днів.

Ускладнення

Часто кір вважається неприємною хворобою легкої або середньої тяжкості. Гострою формою кору, як правило, хворіють діти молодшого віку, які недостатньо харчуються, а, особливо, ті, що не отримують достатньо вітаміну А, або коли їх імунна система ослаблена ВІЛ/СНІД чи іншими хворобами.

Як правило, діти не помирають безпосередньо від кору, але від його ускладнень. Ускладнення є найбільш характерними у дітей віком до п'яти років або у дорослих віком від 20-ти років.

Найсерйозніші ускладнення включають сліпоту, енцефаліт (небезпечна інфекція мозку, що спричиняє запалення), гостра форма діареї (можливо призводить до зневоднення), інфекції вуха та гострі дихальні інфекції, такі як, пневмонія, яка являється основною причиною смерті, що викликає кір. Підраховано, що в одного із 1000 хворих розвивається енцефаліт, в той час як про отит (запалення середнього вуха) ЗМІ повідомляють у 5-15% випадків кору, а про пневмонію у 5-10% випадках. Показник летальності у країнах, що розвиваються, коливається, як правило, від 1 до 5%, але може підвищуватися до 25% серед населення з високим рівнем недостатнього харчування та недостатньою медичною допомогою. Люди, які видужують після кору, мають імунітет на все життя.

Група підвищеного ризику

Не імунізовані люди, особливо діти молодшого віку, складають групу підвищеного ризику захворювання на кір та

його ускладнення. Кір також може вражати імунізованих дітей старшого віку, підлітків та молодь. Всі люди, які не мали щеплення або які не мають набутого імунітету через хворобу, можуть стати інфікованими.

Кір може викликати смерті в країнах, що воюють або відновлюють життя після війни, де відбувається цивільний безлад або природні лиха. Захворюваність росте тому, що порушення роботи інфраструктури та служб охорони здоров'я призупиняють проведення планових щеплень. Наявність таборів, що переповнені біженцями та внутрішні зміни збільшують ризик інфекції.

Передача інфекції

Високо контагіозний вірус кору передається повітряно-крапельним шляхом (циркулює у повітря в результаті кашлю та чхання), через тісний контакт з людиною або прямий контакт з виділеннями із носа та горла інфікованої людини. Отже, кір має спрямованість викликати епідемію, що може спричинити багато смертей, особливо, серед дітей молодшого віку, які недостатньо харчуються..

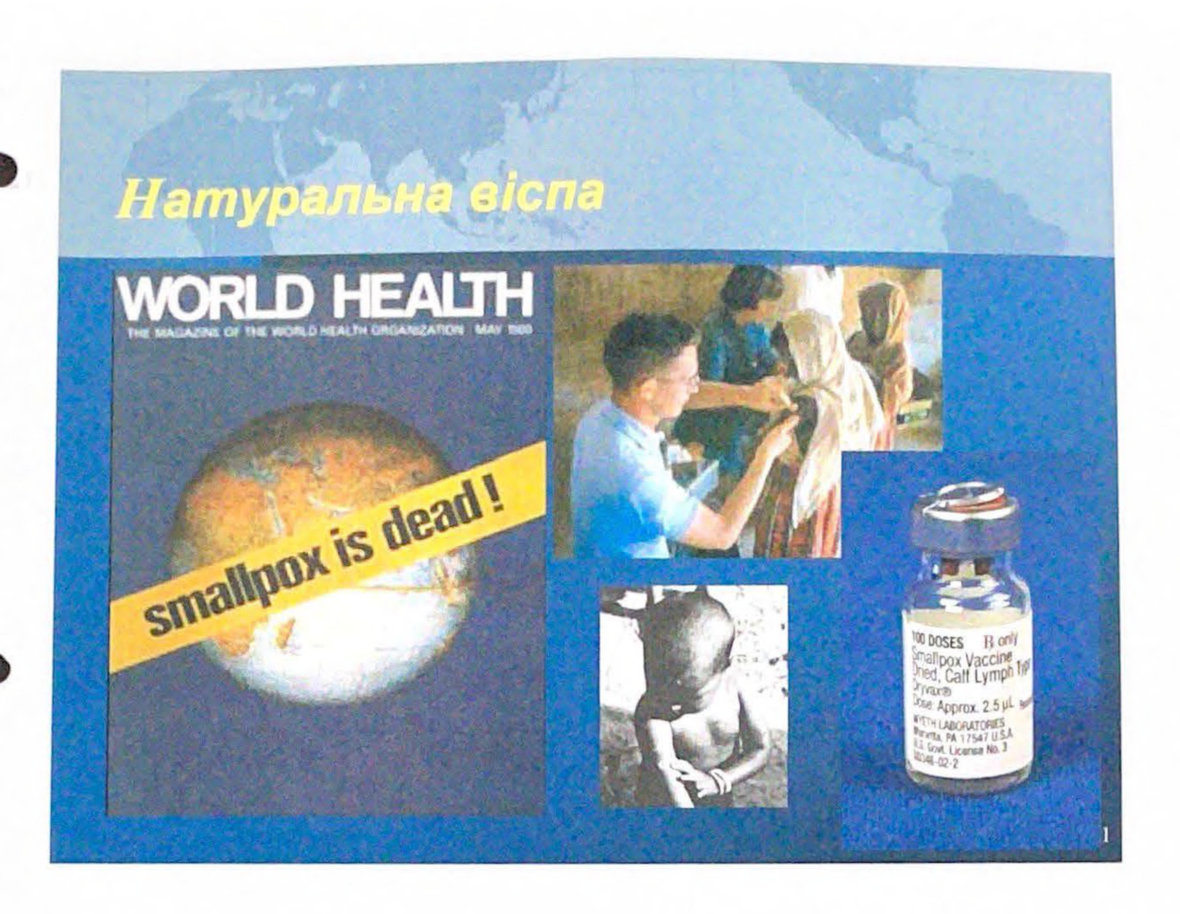
Вірус залишається активним та контагіозним у повітрі або на інфікованих поверхнях до двох годин. Він може передаватися інфікованою людиною від чотирьох днів до появи висипу до чотирьох днів після появи. Якщо людина хвора, висока пропорція людей, які підозрюються у тісному контакті з нею, також стають інфікованими вірусом кору.

Вакцина проти кору

Вакцина проти кору, свинки та краснухи є живою, ослабленою, комбінованою вакциною, що захищає проти вірусів кору, свинки та краснухи. Вперше, вона була ліцензована у комбінованій формі в 1971 році і вміщує найбезпечніші та найефективніші форми кожної вакцини.

Вона виготовляється в лабораторії. Вірус кору беруть з горла інфікованої людини та адаптують його для росту у клітинах ембріону курки. Коли вірус починає краще рости в клітинах ембріону курки, він росте менше на шкірі та і легенях дитини. Коли такий вірус вводять дитині він тільки трохи реплікує, поки зовсім не виводиться з тіла. Така реплікація спричиняє розвиток імунітету в тілі, що присутній все життя у 95% дітей.

Друга доза вакцини рекомендується для захисту тих 5%, у яких не розвинувся імунітет від першої дози та для того, щоб створити «підсилюючий» ефект у людей з імунітетом.

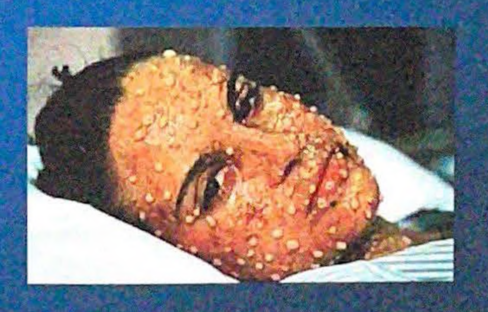




Цілі

Описати епідеміологію натуральної віспи

- Визначити характерні клінічні особливості натуральної віспи
- Переглянути варіанти лікування, запобігання та контролю за натуральною віспою



2



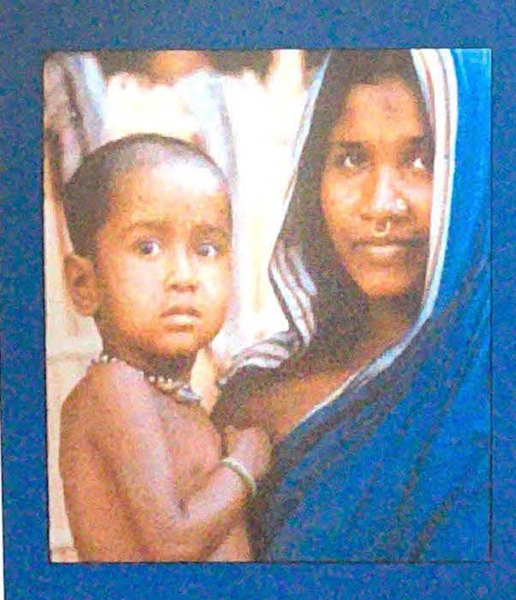
Вступ

- Натуральна віспа спричиняється вірусом *Variola із роду Ortopoxvirus*
- Вперше була описана в китайських папірусах у 4 столітті.
- Вакцина розроблена в кінці 18 сторіччя
- Останній випадок хвороби виник у 1977 році
- Асамблея Всесвітньої організації охорони здоров'я проголосила про ліквідацію натуральної віспи у 1980 році.



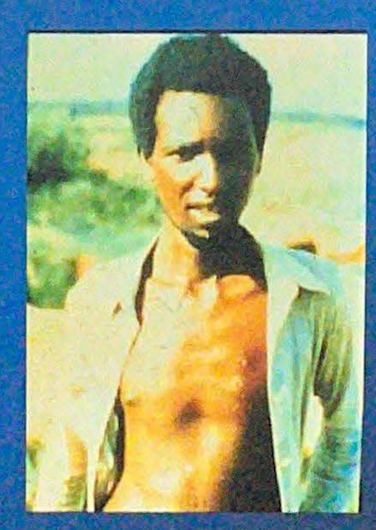


Останні випадки натуральної віспи



Рахіма Бану – 16 жовтня, 1975 рік

Variola Major- Бангладеш



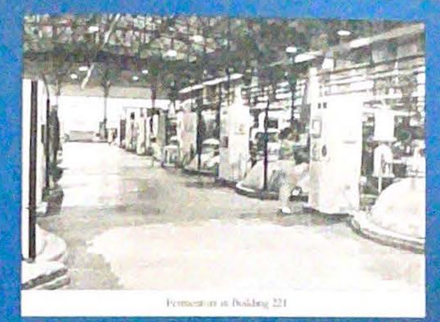
Алі Мао Маалін – 26 жовтня 1977рік

Variola Minor - Сомалі

Smallpok

Натуральна віспа як біологічна зброя

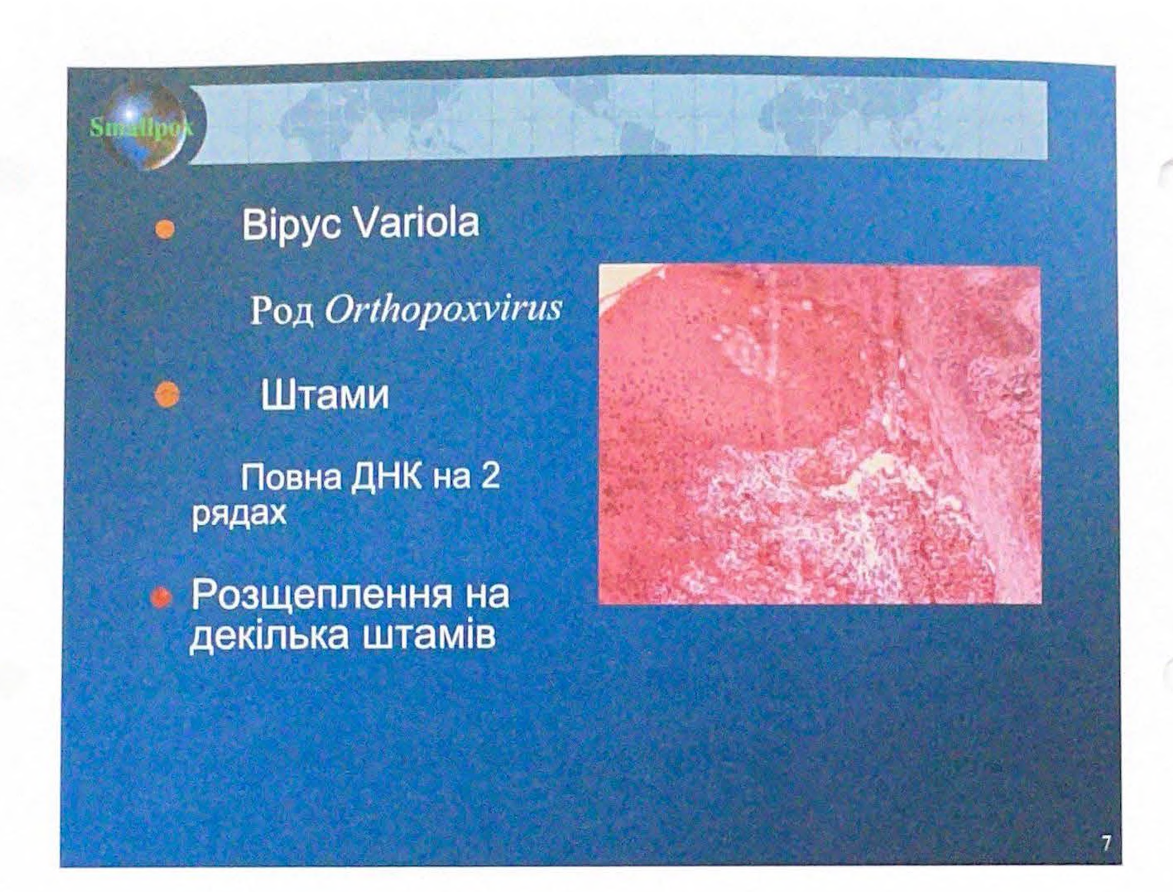

Building 600, where research was conducted


Fermentors in Building 221

- Натуральна віспа були використана як біологічна зброя під час французьких - індійських війн у Сполучених Штатах Америки (1754-1767рр.і)
- Потенційно ефективний агент біологічного тероризму

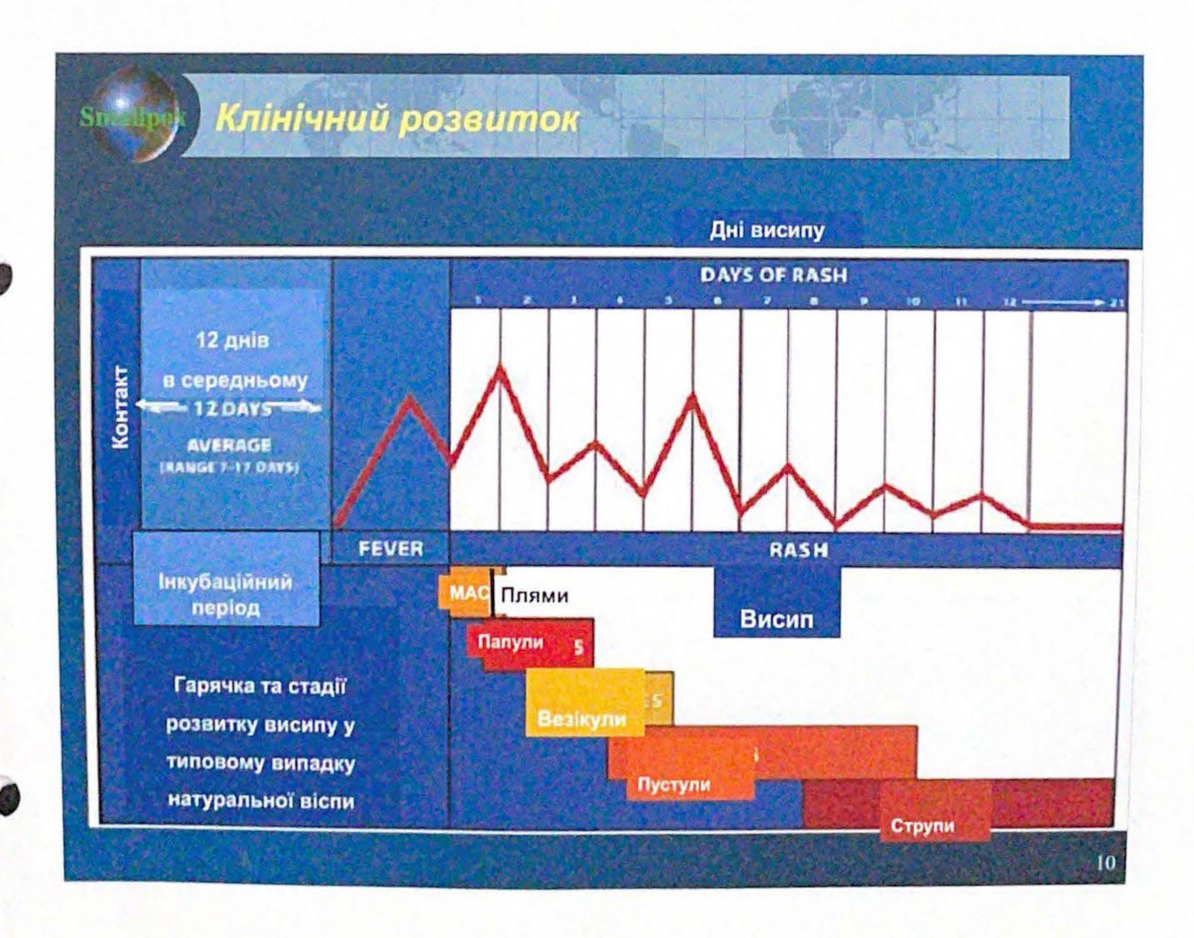


- Так як натуральна віспа була проголошена ліквідованою хворобою, будь-який випадок натуральної віспи повинен вважатися проявом можливого акту біологічного тероризму
- Однак, важливо розуміти та знати, що багато не характерних випадків вітряної віспи можуть бути помилково прийнятими за натуральну віспу.


Smallpox
Вірус Variola
Род *Orthopoxvirus*
Штами
Повна ДНК на 2 рядах
Розщеплення на декілька штамів
7


Smallpox
Резервуар
Офіційно
Тільки у призначених морозильних камерах
8


Спосіб передачі
Люди – це єдиний природний резервуар
Вірус натуральної віспи
До 30% смертності серед людей без щеплень
Випадок натуральної віспи серед загальної кількості населення розглядався би, як навмисне зараження
Передача від людини до людини через контакт або повітряним шляхом
9


Клінічний розвиток
Дні висипу
DAYS OF RASH
Контакт
12 днів
в середньому
12 DAYS
AVERAGE
(RANGE 7-17 DAYS)
FEVER
RASH
Інкубаційний період
Плями
Висип
Папули
Везікули
Пустули
Струпи
Гарячка та стадії розвитку висипу у типовому випадку натуральної віспи
10

Smallpox

Звичайний перебіг натуральної віспи

Зараження

**)
Інкубаційний період
12 днів
(коливається від 7-19 днів)**

**Продромальна стадія
(2-4 дні)**

- **Різким початком гарячки >38.3 С**
- **Втома /біль у м'язах**
- **Головний біль**
- **Нудота/ блювання**
- **Біль у попереку**

НЕ заразна під час продромальної стадії

Початкова стадія висипу

•

Ураження слизової оболонки

Маленькі червоні плями на язику та задній стінці горла

Ураження збільшуються, вкриваються виразками, потім розповсюджують вірус

24 години до появи видимого висипу на шкірі

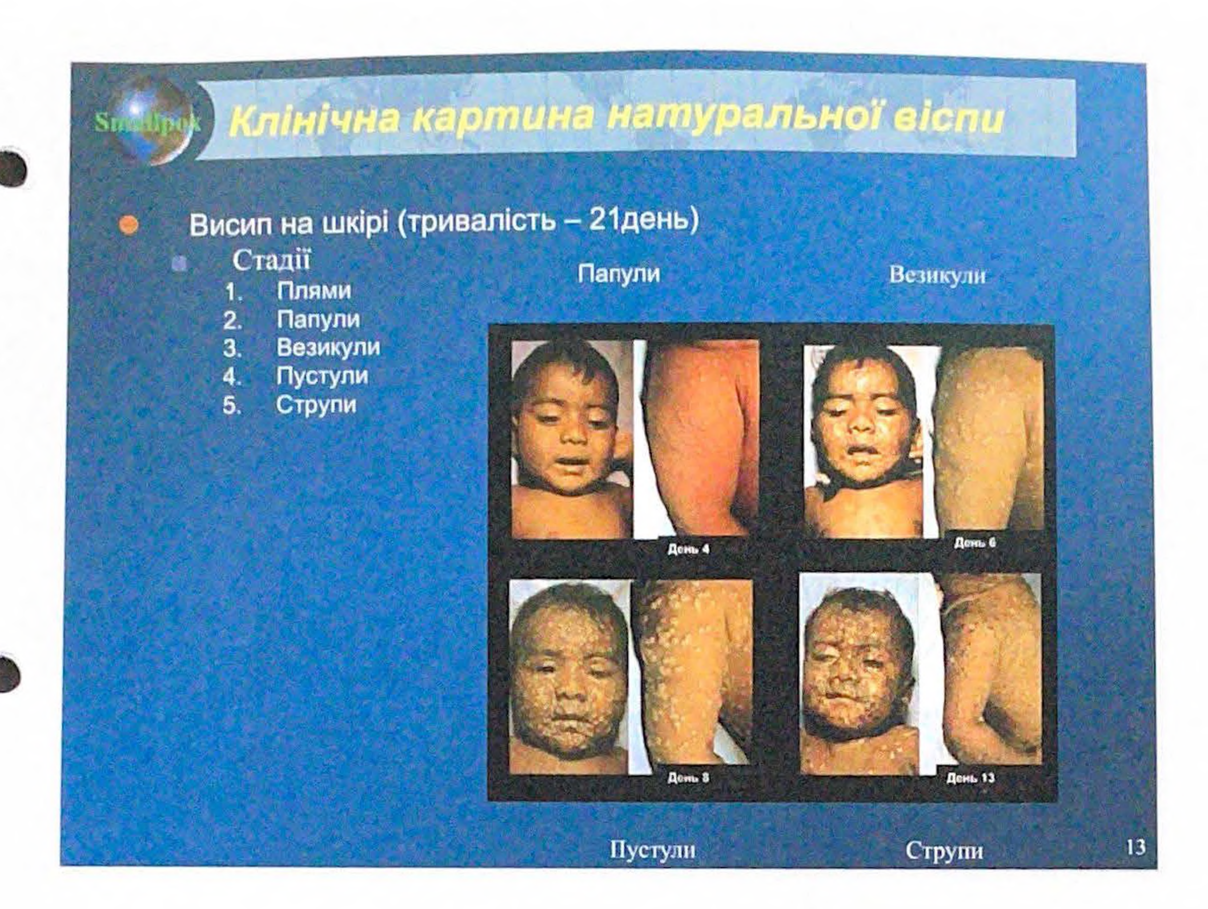
**Стадії висипу
(21 день)**

1 Плями
2. Папули
3. Пухирці
4. Пустули
5. Струпи

Smallpox

Клінічні прояви (клінічна картина)

- Класична форма
  - > 90% випадків
- Атипова форма
  - Не гострий перебіг
  - Спостерігається у людей, хто був щеплений більше 5-ти років назад
- Плоска форма
  - Не характерна, як правило, смертельна
- Геморагічна форма
  - Рідка форма, як правило, смертельна


Smallpox
Клінічна картина натуральної віспи
Висип на шкірі (тривалість – 21день)
Стадії
1. Плями
2. Папули
3. Везикули
4. Пустули
5. Струпи
Папули
Везикули
День 4
День 6
День 8
День 13
Пустули
Струпи
13





Клінічна картина натуральної віспи





- Висип починається і є більш щільним на обличчі, руках та ногах
- Висип на долонях та підошвах виникає у >50% випадках
- Ураження виглядають однаково і розвиваються одночасно на різних стадіях
- Приблизно 1-2 дні на кожну стадію

15



Натуральна віспа в порівнянні з вітряною віспою

НАТУРАЛЬНА ВІСПА

- Глибокі, тяжкі ураження
- Круглі, контури чітко визначені
- Ураження можуть торкатися один одного та мати "ямки"
- Ураження в однаковій стадії розвитку

ВІТРЯНА ВІСПА

- Поверхневі ураження
- Контури нечіткі
- Ураження не торкаються одне одного або мають ямки
- Ураження на різних стадіях розвитку

16



- Підозрілий: Пацієнт з гострою інфекційною хворобою з гарячкою, без іншого діагнозу і такими клінічними характеристиками:
  - Генералізований висип, що складається з глибоко посаджених, твердих, круглих, чітко визначених везикул, які перетворюються на пустули всі в однаковій стадії розвитку
  - Гарячка триває 1-4 дні до початку висипання
  - Висип більш випуклий на обличчі та кінцівках

17



- Ймовірний: Випадок відповідає визначенню підозрілого випадку хвороби та, принаймні, одному із таких стверджень:
  - Епідеміологічний зв'язок з відомим спалахом хвороби або підтвердженим випадком натуральної віспи
  - Будь-які незвичайні обставини, що можуть припускати можливість біологічного тероризму

18



DEPARTMENT OF THE ARMY
OFFICE OF THE VICE CHIEF OF STAFF
201 ARMY PENTAGON
WASHINGTON DC 20310-0201

REPLY TO
ATTENTION OF

MEMORANDUM FOR SEE DISTRIBUTION 10 JAN 2003

SUBJECT: Army Smallpox Vaccination Program Implementation Plan

1. The Department of Defense established the Smallpox Vaccination Program (SVP) to protect the health and safety of our personnel and preserve certain mission critical capabilities. The Army SVP Implementation Plan is enclosed. Commanders will prepare supporting plans to execute this program immediately for servicemembers only, beginning as soon as plan requirements are met. I will transmit a separate directive to the MACOMs directing implementation of the SVP for civilian employees after national labor relation's obligations have been met.

2. The SVP is a commander's responsibility to better ensure force health protection. I want to emphasize four important program components:

- **Identify personnel** to be vaccinated. The Army must vaccinate personnel at occupational risk for smallpox exposure and to ensure mission critical capabilities in accordance with DoD policy. Proper pre-vaccination screening will best ensure people at highest risk for serious adverse events are not vaccinated.
- **Educate personnel** prior to vaccination. I hold Army leaders responsible for the education of their personnel. Your education tools are available at www.smallpox.army.mil. Team with local healthcare personnel to help you.
- **Track vaccinations.** Medical personnel will document vaccinations in Health Records and the Army's automated immunization tracking system, MEDPROS. Commanders will ensure tracking is accomplished and monitor their personnel's compliance using the on-line commander's tools MEDPROS provides. HQDA monitors MACOM compliance metrics using MEDPROS.
- **Get personnel medical evaluation** if they experience symptoms following smallpox vaccination; each deserves individual care and follow-up. Report adverse reactions to the FDA.

4. I urge Army leaders—officers, noncommissioned officers, and civilian supervisors—to give the SVP your personal attention to best protect our Army.

Enclosure

John M. Keane
General, United States Army
Vice Chief of Staff

DACS-ZB
SUBJECT: Army Smallpox Vaccine Program Implementation Plan

DISTRIBUTION:
HQDA (SAILE-ESOH)
HQDA (SAMR-ZA)
HQDA (SARD-ZAX)
HQDA (SAAA)
HQDA (DACS-SM)
HQDA (SAIS-ZX)
HQDA (SAIG-ZX)
HQDA (SAAG-ZX)
HQDA (SAPA-ZX)
HQDA (DAMI-ZX)
HQDA (DAMO-ZX)
HQDA (DAPE-ZX)
HQDA (DASG-ZX)
HQDA (DAAR-ZX)
HQDA (DACH-ZX)
HQDA (DAIM-ZX)
HQDA (SADBU-ZX)

COMMANDER
U.S. ARMY EUROPE, AND SEVENTH ARMY
U.S. ARMY FORCES COMMAND
U.S. ARMY MATERIAL COMMAND
U.S. ARMY TRAINING AND DOCTRINE COMMAND
U.S. ARMY CORPS OF ENGINEERS
U.S. ARMY CRIMINAL INVESTIGATION COMMAND
U.S. ARMY INTELLIGENCE AND SECURITY COMMAND
U.S. ARMY MEDICAL COMMAND
U.S. ARMY MILITARY DISTRICT OF WASHINGTON
U.S. ARMY PACIFIC
U.S. ARMY SOUTH
U.S. ARMY SPACE AND MISSILE DEFENSE COMMAND
U.S. ARMY SPECIAL OPERATIONS COMMAND
EIGHTH U.S. ARMY

MILITARY TRAFFIC MANAGEMENT COMMAND
DIRECTOR, ARMY NATIONAL GUARD
CHIEF, ARMY RESERVE

ARMY SMALLPOX PREPAREDNESS AND VACCINATION PROGRAM IMPLEMENTATION PLAN

REFERENCES: See ANNEX A

1. SITUATION.

a. The Deputy Secretary of Defense approved the Department of Defense (DoD) Smallpox Response Plan and directed execution of the Smallpox Vaccination Program (SVP), in accordance with Food and Drug Administration (FDA) guidelines and consistent with the best practice of medicine, to protect selected personnel at highest risk and preserve certain mission critical capabilities. This program supports the national smallpox preparedness plans, but is tailored to the unique requirements of the Armed Forces.

b. The SVP is a command responsibility as part of force health protection. Commanders are responsible for program implementation, to include education of their personnel, tracking of smallpox vaccinations and compliance with FDA requirements.

c. The Secretary of the Army (SECARMY) is the Executive Agent for the SVP, responsible for: vaccine acquisition and stockpiling; to manage and direct the vaccination of identified personnel within the Uniformed Services consistent with DoD policy, the threat, availability of FDA-approved smallpox vaccine, and priorities established by the Chairman of the Joint Chiefs of Staff; to issue operational instructions to the Services; to serve as a focal point for submission of information from the Services; to monitor Services' implementation; to recommend appropriate SVP changes to the Assistant Secretary of Defense (Health Affairs); to execute the Army's implementation plan; and to report quarterly on program execution.

d. The Office of The Surgeon General, through its Military Vaccine Office (MILVAX) will perform the day-to-day functions assigned to SECARMY for all Executive Agent functions, except vaccine acquisition and stockpiling, and keep the SECARMY informed through the Army's SVP Senior Military Official, The Vice Chief of Staff.

e. The Program Executive Office for Chemical and Biological Defense (PEOCBD)—formerly the Joint Program Office for Biological Defense (JPO-BD)—will perform the function of vaccine acquisition and stockpiling assigned to SECARMY, assuring an adequate supply of smallpox vaccination products, and defining production capabilities on behalf of all Services. PEOCBD will keep the MILVAX informed of all vaccine acquisition, stockpiling, and production issues.

f. The Army will vaccinate the following personnel eligible for smallpox vaccinations per Paragraph 3.a., this plan:

(1) Military personnel;

(2) DA civilian personnel classified as emergency-essential under DoD Directive 1404.10, "Emergency-Essential (E-E) DoD U.S. Citizen Civilian Employees, " 10 Apr 99;

(3) Contractor personnel performing mission essential services as described in DoD Instruction 3020.37, "Continuation of Essential DoD Contractor Services During Crisis," 6 Nov 90, with Change 1 dated 26 Jan 96;

(4) Other personnel categorized as alert forces, as defined in the joint regulation on Immunizations and Chemoprophylaxis (AR 40-562);

(5) Other civilian employees who are designated members of a smallpox response team (e.g., smallpox epidemiological team, treatment team, public health team).

Vaccination is mandatory for personnel in categories 1.f.(1), (2), (3), and (4), except as provided under applicable administrative (ANNEX B) and medical (ANNEX C) exemption policies. For civilian personnel

in category 1.f.(5), vaccination shall not be mandatory; these personnel should be offered and encouraged to receive FDA-licensed smallpox vaccine, unless medically exempted. For vaccinations of civilian personnel, ensure all bargaining obligations are fulfilled IAW Federal Services Labor Management Relations Statute prior to implementation.

(6) In those instances where individuals are not able to take smallpox vaccine due to: (1) an administrative exemption, granted by a commander or supervisor, discussed in detail in ANNEX B; or (2) a medical exemption granted by a privileged healthcare provider (e.g. physicians, nurse practitioners, and physician assistants), discussed in detail in ANNEX C, he/she is still deployable.

2. MISSION. Headquarters Department of the Army (HQDA) implements the DoD Smallpox Response Plan and Smallpox Vaccination Program to preserve certain mission critical capabilities against smallpox (variola virus) and protect selected personnel at highest risk.

3. CONCEPT OF OPERATIONS.

a. **Identify and Vaccinate Eligible Personnel IAW DoD Policy.** The Army will vaccinate personnel in accordance with (IAW) the Office of the Secretary of Defense (OSD) and Joint Chiefs of Staff (JCS) guidance (ANNEX A). The Army will vaccinate designated personnel in stages:

(1) Stage 1a. Smallpox Response Teams. DoD's Smallpox Response Plan requires these response teams, including designated special mission units, medical epidemiological response teams, and the Army National Guard Civil Support Teams (CST).

(2) Stage 1b. Selected Healthcare Workers. The Army will vaccinate selected healthcare workers at most installations, especially those with inpatient capabilities. This will give the Army the capability to respond to a smallpox attack IAW the DoD Smallpox Response Plan.

(3) Stage 2. Designated forces that constitute certain mission-critical capabilities. These include certain forces deployed or assigned overseas, forces that would be expected to deploy in a contingency, and forces that enable such contingency forces to deploy. At this time, the Secretary of Defense has limited implementation of this stage to that part pertaining to U.S. Central Command's missions. Army will publish supplemental classified guidance for Stage 2 implementation.

(4) Near-term SVP implementation may also include other personnel determined by the Assistant Secretary of Defense for Health Affairs (ASD(HA)), in consultation with the Chairman of the Joint Chiefs of Staff (CJCS), to be at higher risk of exposure to Smallpox. Commanders may submit requests for exceptions for others not covered by DoD policy to be vaccinated against smallpox through MACOMs to HQDA, Office of The Surgeon General, Military Vaccine Agency, 5109 Leesburg Pike, Falls Church, VA 22041 for coordination and approval with ASD(HA) and CJCS.

b. **Mandatory Vaccination Policy.** The smallpox vaccine is mandatory for designated personnel in paragraphs 1.f.(1), (2), (3), and (4) this plan, unless specifically exempted through: (1) an administrative exemption, granted by a commander or supervisor, discussed in detail in ANNEX B; or (2) a medical exemption granted by a privileged healthcare provider (e.g. physicians, nurse practitioners, and physician assistants), discussed in detail in ANNEX C, using the standard form at http://www.smallpox.army.mil/media/pdf/Vacciniainitial.pdf. For civilian personnel in category 1.f.(5), vaccination shall not be mandatory; these personnel should be offered and encouraged to receive FDA-licensed smallpox vaccine, unless medically exempted. For vaccinations of civilian personnel, ensure all bargaining obligations are fulfilled IAW Federal Services Labor Management Relations Statute prior to implementation. As with all immunizations, military personnel do not have the option to refuse immunization. IAW AR 600-20, Army Command Policy, commanders can order their soldiers to be immunized. Although each case will be determined on its own merits, soldiers refusing an order may face adverse administrative action or disciplinary action under the Uniform Code of Military Justice. Coordinate disciplinary actions subsequent to any vaccination refusal with your servicing judge advocate or legal advisor. ANNEX B discusses vaccination refusal management further.

c. **Vaccine Requisition and Distribution.** The U.S. Army Medical Materiel Agency (USAMMA) will coordinate the distribution of the vaccine and ancillary products to the supporting medical supply activities of all Services per ANNEX D. End-users will directly requisition vaccine IAW USAMMA guidelines in ANNEX D as required for SVP sustainment.

d. **Education of Personnel to be Vaccinated.** Commanders and Army leaders at all levels are responsible to educate their personnel before vaccination and identify people exempt from smallpox vaccination. At a minimum, Commanders and other leaders will brief their eligible personnel and provide them a copy of the informational trifold as outlined in ANNEX E. Your local medical treatment facility will maintain a stock of trifolds for your use. Team with local healthcare providers and other subject matter experts (e.g., staff judge advocate, public affairs offices) to assist with this education, screening for exemptions, and answering questions upfront. Current education tools are always available at www.smallpox.army.mil. ANNEX E also details the Army's public affairs strategy.

e. **Options For Personnel with Medically Exempt Household Contacts.** Commanders will actively manage their personnel who are temporarily medically exempt from smallpox vaccination due to a household contact who has a medical contraindication and ensure their vaccination when that household contact exemption no longer applies. Commanders basically have two options, either (1) arrange for alternate housing from day of vaccination until the vaccination scab falls off (about 14 to 21 days), or (2) vaccinate the person when the exemption no longer applies (e.g., after family separation during mobilization or at time of deployment). See Appendix 1 to ANNEX C for examples of acceptable and unacceptable situations.

f. **Adverse Event Management.** Provide people with appropriate medical evaluation if they experience symptoms following smallpox vaccination. Some symptoms and complaints may be caused by the vaccine—others may not—but each deserve appropriate medical attention, individual concern, and empathy. If symptoms persist, providers, leaders, or patients may contact the Walter Reed Vaccine Healthcare Center at 202.782.0411, for appropriate consultation, advice, and specialized medical management. Report adverse reactions IAW ANNEX C, AR 40-562, and AR 40-3. MILVAX will track reports of adverse events and report to The Surgeon General routinely.

g. **Immunization Tracking and Compliance.** Commanders and healthcare personnel have dual roles ensuring smallpox vaccinations are documented in healthcare records and the Army's automated immunization tracking system, the Medical Protection System (MEDPROS) IAW ANNEXES C and J. The HQDA standard for SVP execution is 90% compliance of eligible personnel receiving their smallpox vaccinations or having exemptions noted in MEDPROS. HQDA will monitor Army MACOMs' performance using these metrics through MEDPROS. MEDPROS not only tracks the immunization record, but offers commanders a powerful tool to manage SVP immunization within their units from their desktop computer.

h. **Coordinating Vaccination.** To deliver this immunization, the Army will use military medical assets (including those organic to the units); Veterans Administration Sharing Agreement, an MOA with the Public Health Service's Federal Occupation Health Division, and a private sector contract to deliver this immunization. The U.S. Army Medical Command (USAMEDCOM), Army National Guard (ARNG) (ANNEX G), and U.S. Army Reserve (USAR) (ANNEX H) will assist these medical providers to execute this plan.

4. RESPONSIBILITIES.

a. Army MACOMs.

(1) Develop supporting plans to execute smallpox immunizations IAW this plan.

(2) Incorporate smallpox vaccination information IAW ANNEX E into Command Information Programs.

(3) Implement procedures to ensure that in-processing and out-processing at subordinate installations include a screen to ascertain smallpox vaccination status and ensure compliance with this plan.

(4) Direct installations develop local supporting plans to the DoD Smallpox Response Plan.

b. Office of The Surgeon General/US Army Medical Command.

(1) Provide vaccination support in coordination with Army MACOMs in support of their vaccination plans.

(2) Provide vaccination support to the Army National Guard and U.S. Army Reserves IAW ANNEXES H and I, respectively.

(3) Provide vaccination support to other Services IAW OASD(HA) guidance.

(4) Provide vaccine and ancillary supplies IAW ANNEX D, to units conducting vaccinations.

(5) Develop and disseminate medical information, policy, and doctrine as required.

(6) Receive and consolidate reports of adverse events from all Services. Provide summary reports to The Surgeon General.

(7) Issue specific guidance and direct identification of Stage 1b healthcare workers within MEDCOM.

(8) Establish smallpox vaccination training standards and facilitate training and training documentation.

(9) As part of MEDCOM's Organization Assessment Program (OAP), perform audits of immunization records for quality-assurance purposes, to assure completeness of data entry and agreement of paper and electronic immunization records.

c. The Program Executive Office for Chemical and Biological Defense (PEOCBD).

(1) Execute procedures to procure and store the smallpox vaccine IAW OSD guidelines.

(2) Program future resources necessary to support the Department's Medical Biological Defense Program against smallpox.

5. COORDINATING INSTRUCTIONS.

a. Direct coordination with Navy, Marine Corps, Air Force, and Coast Guard medical facilities is authorized.

b. Funding for vaccine will be provided by the PEOCBD. Ancillary supplies will be funded from the Defense Health Program (DHP).

c. For military personnel, MACOMs have the authority to execute this plan and vaccinate immediately upon meeting the requirements for: appropriate identification of personnel to be vaccinated IAW DoD policy and ANNEX C; vaccine distribution and storage; prevaccination education; documentation and tracking vaccinations and compliance with the program; and ability to evaluate and report suspected adverse reactions, outlined in this plan.

d. Before beginning smallpox vaccinations at any installation, preventive medicine staff will contact their counterparts at city, county, and state public health departments to inform them that smallpox vaccinations will begin in the near future.

e. Proponent of this plan is the Office of The Surgeon General, Directorate of Healthcare Operations, Military Vaccine Agency, DASG-HCA, DSN 761-5101, COMM (703) 681-5101.

6. ANNEXES.

a. ANNEX A, REFERENCES
b. ANNEX B, ADMINISTRATIVE CONSIDERATIONS AND GUIDANCE
c. ANNEX C, MEDICAL CONSIDERATIONS AND GUIDANCE
d. ANNEX D, LOGISTICS
e. ANNEX E, EDUCATION/COMMUNICATIONS PLAN
f. ANNEX F, PERSONNEL
g. ANNEX G, ARMY NATIONAL GUARD
h. ANNEX H, U.S. ARMY RESERVE
i. ANNEX I, DEPARTMENT OF THE ARMY CIVILIANS AND DOD CONTRACTORS
j. ANNEX J, IMMUNIZATION TRACKING

ANNEX A - REFERENCES

1. Department of Defense Directive (DoDD) 6205.3, DoD Immunization Program for Biological Warfare Defense, 26 November 1993. http://www.dtic.mil/whs/directives/corres/pdf/d62053_112693/d62053p.pdf

2. AR 40-2, Army Medical Treatment Facilities General Administration, 15 March 1983. http://www.usapa.army.mil/pdffiles/r40_2.pdf

3. AR 40-68, Quality Assurance Administration, 20 December 1989. http://www.usapa.army.mil/pdffiles/r40_68.pdf

4. Memorandum of Understanding Between the U.S. Army Medical Command and U.S. Army Reserve Command, 11 May 1995.

5. CDC Smallpox Response Plan, Guide B, Vaccination Guidelines for State & Local Health Agencies, 23 September 2002. http://www.bt.cdc.gov/DocumentsApp/Smallpox/RPG/.

6. CDC Smallpox Response Plan, Annex 2, Guidelines for Smallpox Vaccination Clinics, 23 September 2002. http://www.bt.cdc.gov/DocumentsApp/Smallpox/RPG/.

7. CDC Smallpox Response Plan, Annex 3, Vaccine Adverse Events Reporting, 23 September 2002. http://www.bt.cdc.gov/DocumentsApp/Smallpox/RPG/.

8. US Army Medical Department. Clinical Guidelines for Managing Adverse Events After Vaccination, 22 August 2002. http://www.anthrax.mil/media/pdf/cpguidelines.pdf and http://www.anthrax.mil/media/pdf/algorithm.pdf.

9. National Vaccine Advisory Committee. Adult immunization programs in nontraditional settings: Quality standards and guidance for program evaluation. *MMWR* 2000; 49(RR-1): 1-13. http://ftp.cdc.gov/pub/Publications/mmwr/rr/rr4901.pdf.

10. Advisory Committee on Immunization Practices. Vaccinia (smallpox) vaccine. *MMWR* 2001; 50(RR-10): 1-25. http://www.cdc.gov/mmwr/PDF/rr/rr5010.pdf. Supplemented by Summary of October 2002 ACIP Smallpox Vaccination Recommendations, 21 October 2002, http://www.bt.cdc.gov/agent/smallpox/vaccination/acip-recs-oct2002.asp.

11. DoD Smallpox Response Plan, version 3.1, 29 September 2002, http://www.smallpox.army.mil/media/pdf/DODSpoxPlan.pdf

12. AR 40-3, Medical, Dental, and Veterinary Care, 30 July 1999.

13. DEPSECDEF Memo, Subject: Department of Defense Smallpox Response Plan, 30 September 2002.

14. ASD(HA) Memo, Subject: Clinical Policy for the DoD Smallpox Vaccination Program (SVP), 26 November 2002.

15. USD(P&R) Memo, Subject: Policy on Administrative Issues Related to Smallpox Vaccination Program (SVP), 13 December 2002.

16. DoD Directive 1404.10, "Emergency-Essential (E-E) DoD U.S. Citizen Civilian Employees," 10 April 1999.

17. DoD Instruction 3020.37, :Continuation of Essential DoD Contractor Services During Crisis, " 6 November 1990, with Change 1 dated 26 January 1996.

ANNEX B - ADMINISTRATIVE CONSIDERATIONS AND GUIDANCE

1. Administrative Exemptions.

a. This section provides criteria for administrative exemptions for selected personnel subject to the DoD Smallpox Vaccination Program (SVP). It does not apply to medical exemptions. Army commanders and civilian supervisors at all levels are designated as exemption authority to grant administrative exemptions per this Annex for the DoD SVP.

b. Administrative exemption is applicable to retiring and separating personnel (without Reserve Component (RC) obligations and who do not plan to immediately re-enlist) and civilian employees and contractor personnel leaving a position subject to the SVP with 30 days or less of service or employment remaining. This administrative exemption does not apply to personnel whom the commander determines shall receive the vaccine because of overriding mission requirements.

c. Exemption authorities shall exempt from the SVP those personnel separating within 30 days (as described further below) who meet all of the following conditions: (a) they are not currently assigned or deployed to a designated higher threat area; (b) they are not scheduled to perform duty in a designated higher threat area; and, (c) the exemption authority has not directed vaccination because of overriding mission requirements. Personnel who meet these criteria should immediately identify themselves to their commanders and supervisors.

d. To calculate the 30-day period, the following specifications apply. For retiring or separating military personnel, the applicable period is 30 days prior to their approved date of retirement or separation. RC members must have approved retirement orders to be effective within 30 days, reassignment date to the Individual Ready Reserve (IRR), or expirations of enlistment within 30 days prior to consideration for exemption from the vaccine. Those personnel who are separating from active duty but continuing service with the Selected Reserve are NOT exempt. For EE and contractor personnel subject to the SVP because of performance of essential contractor services, the applicable period is 30 days prior to the effective date of retirement, resignation, separation, or reassignment out of a position subject to the SVP. All other reserve personnel categories (e.g. IRR, Individual Mobilization Augmentee (IMA)), when mobilized, are subject to smallpox vaccination per this plan and DoD guidance.

e. Granting administrative exemptions is a personnel function, usually controlled by an individual's unit. Exemption authorities will use the following exemption codes for electronic tracking of administrative exemptions in all vaccine recipients in MEDPROS, the Army's automated immunization tracking system (See ANNEX J):

Code	Meaning	Explanation or Example	Duration
AD	Administrative, Deceased	Servicemember/civilian is deceased	Indefinite
AL	Administrative, Emergency Leave	Servicemember/civilian is on emergency leave	Max 1 month
AM	Administrative, Missing	Missing in action, prisoner of war	Indefinite
AP	Administrative, PCS	Permanent change of station	Max 3 months
AR	Administrative, Refusal	UCMJ Actions	Until resolution
AS	Administrative, Separation	Discharge, separation, retirement	Indefinite
AT	Administrative, Temporary	AWOL, legal action pending	Max 3 months

2. Smallpox Vaccine Refusal Management for Servicemembers. Commanders will manage refusal to take the smallpox vaccine (or any vaccine), as they would address any refusal to obey a lawful order and IAW AR 600-20, Army Command Policy. Always coordinate vaccine refusal management with your servicing judge advocate or legal advisor. See Annex I for guidance on civilian employee refusal to take the smallpox vaccine.

a. Per AR 600-20, paragraph 5-4, "A soldier on active duty or active duty for training will usually be required to submit to medical care considered necessary to preserve his or her life, alleviate undue suffering, or protect or maintain the health of others. Commanders may order the examination of any soldier in their command when warranted. The medical treatment facility commander will determine if hospitalization of the soldier is appropriate." In accordance with AR 600-20, Army Command Policy, commanders can order their soldiers be immunized. Although each case will be determined on its own merits, soldiers refusing an order may face adverse administrative action and/or disciplinary action under the provisions of The Uniform Code of Military Justice, Article 92, Failure to obey order or regulation.

b. Immunizations. Commanders will ensure that soldiers are continually educated concerning the intent and rationale behind both routine and theater-specific or threat-specific military immunization standards. Immunizations required by AR 40-562 or other legal directive may be given involuntarily (except as prescribed in paragraph 5-6 of this regulation). The intent of this authorization is to protect the health and overall effectiveness of the command, as well as the health of the individual soldier.

c. Per AR 600-20, "Under normal circumstances, actions will not be taken to involuntarily immunize soldiers." [i.e., hold them down or otherwise restrain them]

d. Commanders will:

(1) Ensure soldiers understand the purpose of the vaccine.

(2) Ensure soldiers are advised of both the endemic, natural threat and potential use as a biological weapon agent.

(3) Ensure soldiers are educated about the vaccine and have been afforded the opportunity to discuss concerns with medical authorities.

(4) Counsel the soldier, in writing, on his or her requirement to be immunized and ramifications for failure to follow a lawful order.

(5) Order the soldier to receive the vaccination.

e. Per AR 600-20, para 5-4.c.(2)(c), "When a General Court-Martial Convening Authority (GCMCA) or his delegated representative determines that conditions of imminent threat exist (where the threat of naturally occurring disease or use of biological weapons is reasonably possible) soldiers may be involuntarily immunized. Involuntary immunization(s) will not be ordered by a commander below the GCMCA unless authority to do so has been properly delegated by the GCMCA. Prior to ordering involuntary immunizations, all of the steps outlined above should be followed, situation permitting. In performing this duty, unit personnel will only use the amount of force necessary to assist medical personnel in administering the immunization."

ANNEX C - MEDICAL CONSIDERATIONS AND GUIDANCE

1. REFERENCES.

a. Air Force Joint Instruction 48-110, Army Regulation 40-562, BUMEDINST 6230.15, and CG COMDTINST M6230.4E, Immunizations and Chemoprophylaxis, November 1, 1995. http://www.e-publishing.af.mil/pubfiles/af/48/afji48-110/afji48-110.pdf

b. Centers for Disease Control and Prevention, Advisory Committee on Immunization Practices. General Recommendations on Immunization. MMWR 2002; 51(RR-2): 1-35. ftp://ftp.cdc.gov/pub/Publications/mmwr/rr/rr5102.pdf.

c. Assistant Secretary of Defense for Health Affairs Memorandum, Clinical Policy for the DoD Smallpox Vaccination Program (SVP), November 26, 2002.

d. US Army Medical Department. Clinical Guidelines for Managing Adverse Events After Vaccination, 22 August 2002. http://www.anthrax.mil/media/pdf/cpguidelines.pdf and http://www.anthrax.mil/media/pdf/algorithm.pdf.

e. Vaccine Healthcare Center website, http://www.vhcinfo.org/.

f. Vaccine Adverse Event Reporting System online reporting, www.vaers.org or https://secure.vaers.org/VaersDataEntryintro.htm.

g. Smallpox Vaccine (Dryvax) Insert. http://www.fda.gov/cber/label/smalwye102502LB.pdf.

h. DoD Smallpox Vaccination Program Website: www.smallpox.army.mil.

i. Memorandum, Commander, US Army Medical Command, Preparing to Defend Against Smallpox. December 23, 2002. http://www.smallpox.army.mil/media/pdf/prepDefmemo1.pdf.

j. Advisory Committee on Immunization Practices. Vaccinia (smallpox) vaccine. *MMWR* 2001; 50(RR-10): 1-25. http://www.cdc.gov/mmwr/PDF/rr/rr5010.pdf. Supplemented by Summary of October 2002 ACIP Smallpox Vaccination Recommendations, 21 October 2002, www.bt.cdc.gov/agent/smallpox/vaccination/acip-recs-oct2002.asp.

k. Army Regulation 600-110, Identification, Surveillance, and Administration of Personnel Infected with Human Immunodeficiency Virus (HIV), 1 June 1996.

2. GENERAL INFORMATION.

a. Vaccine Description.

(1) Smallpox Vaccine, Dryvax®, protects more than 95% of healthy people who receive it. Smallpox vaccine contains live vaccinia viruses made from calf lymph, which cross-protect against variola virus, the virus that causes smallpox. Smallpox vaccine will be administered in the standard full-strength concentration (as per original labeled reconstitution instructions), unless the CDC, FDA, or other responsible health authority issues explicit instructions to the contrary.

(2) The smallpox vaccine, dried, is manufactured from purified, concentrated lyophilized calf lymph. Polymyxin B sulfate, dihydrostreptomycin sulfate, chlortetracycline hydrochloride, and neomycin sulfate are added during processing and trace amounts may be in the final product. The diluent for Dryvax® contains 50% glycerin, and 0.25% phenol in Sterile Water for injection, USP. Once reconstituted, the vaccine contains approximately 100 million infectious vaccinia viruses per mL, 100 doses per vial. Plan carefully to minimize vaccine wastage that may result from discarding partially used vials.

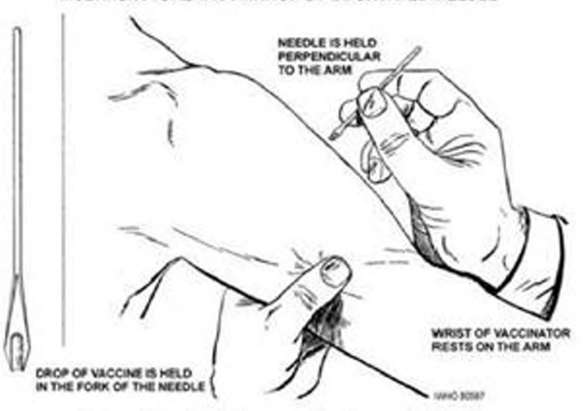
(3) Store reconstituted Dryvax® in the refrigerator between 2° to 8°C (36°to 46°F) Reconstituted Dryvax® may be used for 60 days, according to Dec 02 information from the manufacturer and the FDA, posted on the www.smallpox.army.mil website. This interval may increase to 90 days, if later authorized by the manufacturer and FDA.

(4) Indications and usage. The Advisory Committee for Immunization Practices (ACIP) recommends vaccination to prevent infection with variola virus, the causative agent of smallpox infection. Commanders must take care to identify people who should be exempted from smallpox vaccination due to underlying health conditions.

Figure 1. Proper technique for using bifurcated needle to immunize with smallpox vaccine.







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b. Dosage, Administration, and Response Issues.

(1) Dosage.

Smallpox vaccine is administered in one dose. Inoculate the recipients with a bifurcated needle holding a drop of vaccine and press 3 times for primary vaccination, or 15 times for revaccinations into the skin of the upper arm. Evidence of a prior primary smallpox vaccination includes documentation, or a characteristic Jennerian scar. Presumptive evidence includes entry into U.S. military service before 1984, or birth in the United States before 1970. In general, people should be revaccinated 5 years after

their primary smallpox vaccination and 10 years after subsequent smallpox revaccinations. Specific laboratory workers involved with orthopox virus research may require more frequent vaccination.

(2) Administration Issues.

(a) Vaccination procedures will be consistent with information provided in refs a. and c. Bifurcated needle method is indicated for this vaccine. Preferred injection site is the skin over the deltoid muscle or the posterior aspect of the arm over the triceps muscle. Do not vaccinate near the site of an active lesion. Avoid tattooed skin and skin folds. See Figure 1.

(b) Multiple Vaccinations.

1 Dryvax® may be administered concurrently with other inactivated vaccines, if necessary, or at any interval before or after inactivated vaccines, consistent with ACIP recommendations. See the following paragraph for operational examples. Except for varicella vaccine, smallpox vaccine may be administered simultaneously with other live virus vaccines. To avoid confusion in ascertaining which vaccine may have caused post-vaccination skin lesions or other adverse events, and to facilitate managing such events, varicella vaccine and smallpox vaccine should only be administered 4 weeks apart or greater. If not given simultaneously, live virus vaccines should be separated by 4 weeks or more. Do not administer other vaccines near an active smallpox vaccination site.

2 Ideally, give smallpox vaccine 2 weeks before inactivated vaccines, such as anthrax vaccinations, so those with post-smallpox vaccination malaise between days 8-12 recover before subsequent vaccination. If deployment obligations do not allow this much time, give anthrax vaccination #1 on "day 0." Systemic symptoms, if they occur, would be resolved within 72 hours. Smallpox vaccinations may then be scheduled for "day 3" or "day 4" or later. Distribute any other needed vaccinations (e.g., tetanus-diphtheria, typhoid) on "day 0" or with subsequent anthrax vaccinations.

(c) Needles should be discarded in labeled, puncture-proof containers to prevent inadvertent needle stick injury or reuse.

(d) Because of the nature of the vaccine container, and method of administration, vaccinators' hands should be washed with soap and water or cleansed with an alcohol-based waterless antiseptic solution before and after each patient contact.

(e) Cleansing of the vaccination site may be performed with soap and water, followed by water only, and then drying. Acetone or alcohol may be used only if adequate time is allowed for it to evaporate or if the site is wiped dry with (non-sterile) gauze, to prevent unintentional inactivation of the live virus vaccine.

(f) Practical Tips.

1 During pre-vaccination screening, using the DoD standard screening form (medical note at http://www.smallpox.army.mil/media/pdf/Vacciniainitial.pdf), remind immunization personnel to overcome their tradition of requiring documentation of prior vaccination. Accept oral history of prior smallpox vaccination. Supplement with records, look for an earlier vaccination scar, accept birth before 1971 (i.e., 1 year of age in 1972), or accept military entry before 1984 as presumptive evidence of prior vaccination.

2 Have one or more physicians, physician assistants, or nurse practitioners on site to resolve uncertainties over eczema and atopic dermatitis (or making appropriate clinical referrals), especially in the early norming phases of the SVP.

3 Allow ample time to resolve people's questions. If possible, separate the education-and-screening day from vaccination day.

4 On vaccination day, at the vaccination station, use a team of two vaccinators who trade off duties. One administers the vaccination jabs, while the other acts as blotter, bandager, and documenter. Documentation should include whether the vaccinator sees trace blood, petechia(e), or frank bleeding, as an aid to assure the vaccinator uses sufficient pressure. Have an additional staff member assure completeness of all forms.

5 Locate the vial of smallpox vaccine toward the back of the vaccination station, so that items are not passed over an open vial. A hole may be carved in a Styrofoam block to prevent the small vial from being accidentally bumped and spilled. During prolonged vaccination sessions, place the vial on a cooling (but not freezing) block, tray, or plate.

6 Flight surgeons should record background rates of "duties not including flying" (DNIF) among aviators before initiating smallpox vaccinations, to determine effects of smallpox vaccination on DNIF rates.

7 Use the standard DoD follow-up note for checking vaccination takes and assessing adverse events (http://www.smallpox.army.mil/media/pdf/VacciniaFollowup.pdf).

8 Thirty-day diary cards are available for clinical or personal use (http://www.smallpox.army.mil/media/pdf/diarycard.pdf).

(3) Care of the Vaccination Site.

(a) Vaccinia virus can be cultured from the site of primary (first) vaccination beginning at the time of development of a papule (i.e., 2 to 5 days after vaccination) until the scab separates from the skin lesion (i.e., 14-21 days after vaccination). During that time, care must be taken to prevent spread of the virus to another area of the body or to another person by inadvertent contact. Disease transmission from intact scabs is unlikely, but high-risk individuals may be vulnerable to scab particles.

(b) The most critical measure in preventing inadvertent contact spread is thorough hand washing after changing the bandage or any other contact with the vaccination site, using an alcohol-based waterless antiseptic solution, or soap and water.

(c) To avoid secondary infection, commanders and noncommissioned officers will direct physical activities so that smallpox vaccination sites are not subject to undue pressure (pressure reasonably likely to burst a pustule), rubbing, or immersion sufficiently prolonged to cause maceration or secondary infection. Activities that complicate vaccine site care and cleanliness should be avoided during the post-vaccination healing period. Avoid contact sports, such as wrestling. Avoid immersion in public pools or spas.

(d) If bandages are used to cover the site in a medical setting, dispose of contaminated bandages and the vaccination scab as biohazardous waste. In other settings, dispose of these items in sealed plastic bags (e.g., Ziploc® bag). Clothing, towels, sheets, or other cloth materials that have had contact with the site can be decontaminated with routine laundering in hot water with detergent or bleach. Normal bathing can continue, but the vaccination site should otherwise be kept dry. Avoid rubbing the vaccination site.

(e) Recently vaccinated healthcare workers should minimize contact with unvaccinated patients, particularly those with immune deficiencies, until the scab falls off. Even patients vaccinated in the past may be at increased risk due to current immunodeficiency. If contact with unvaccinated patients is essential and unavoidable, healthcare workers can continue to have contact with patients, including those with immune deficiencies, as long as the vaccination site is well-covered and thorough hand-hygiene is maintained. In this setting, a more occlusive dressing might be appropriate. Semi-permeable polyurethane dressings (e.g., Opsite®, Tegaderm®, Cosmopore®) are effective barriers to vaccinia and recombinant vaccinia viruses. To prevent accumulation of exudates, cover the vaccination site with dry gauze, and then apply the dressing over the gauze. The dressing should also be changed daily or every

few days (according to type of bandaging and amount of exudates), such as at the start or end of a duty shift. Military treatment facilities should develop plans for site-care stations, to monitor workers' vaccination sites, promote effective bandaging, and encourage scrupulous hand hygiene. Wearing long-sleeve clothing can further reduce the risk for contact transfer.

(4) Vaccination-Response Assessment. Assessment of vaccine "take" is required for healthcare workers and for members of smallpox response teams who will travel into a smallpox outbreak area. Other persons receiving vaccine should also have vaccine "take" assessed. To assess vaccine take, medical personnel trained in vaccination evaluation will inspect the vaccination site at 6 to 8 days after vaccine administration. Reactions will be categorized as "Major Reaction" or "Equivocal" in accordance with the World Health Organization (WHO) and FDA-approved product information (package insert). Definitions are below paragraphs 2.b.(4)(a) and (b). To accommodate individuals for whom "take" assessment is not feasible or is otherwise missed, all persons receiving smallpox vaccine will be educated on the expected smallpox vaccination reaction and instructed to report back to a vaccination clinic if they do not develop a characteristic response.

(a) Major Reaction. Indicates that virus replication has taken place and vaccination was successful. Major (i.e., primary) reaction is defined as a vesicular or pustular lesion or an area of definite palpable induration or congestion surrounding a central lesion that might be a crust or an ulcer. The usual progression of the vaccination site after primary vaccination is as follows:

- The inoculation site becomes reddened and pruritic 3-4 days after vaccination.
- A vesicle surrounded by a red areola then forms, which becomes umbilicated and then pustular by days 7--11 after vaccination.
- The pustule begins to dry; the redness subsides; and the lesion becomes crusted between the second and third week. By the end of approximately the third week, the scab falls off, leaving a permanent scar that at first is pink in color but eventually becomes flesh-colored.

Skin reactions after revaccination might be less pronounced with more rapid progression and healing than those after primary vaccinations. Revaccination is considered successful if a pustular lesion is present or an area of definite induration or congestion surrounding a central lesion (i.e., scab or ulcer) is visible upon examination 6--8 days after revaccination.

(b) Equivocal Reaction. Indicates a possible consequence of immunity adequate to suppress viral multiplication or allergic reactions to an inactive vaccine without production of immunity. Equivocal reaction, including accelerated, modified, vaccinoid, immediate, early, or immune reactions, are defined as all responses other than major reactions. If an equivocal reaction is observed, vaccination procedures should be checked and the vaccination repeated by using vaccine from another vial, if available. Difficulty in determining if the reaction was blunted could be caused by immunity, insufficiently potent vaccine, or vaccination technique failure. If the repeat vaccination by using vaccine from another vial fails to elicit a major reaction, healthcare providers should consult a military allergist-immunologist.

(5) Revaccination. If a person does not manifest a characteristic vaccination response 6 to 8 days after smallpox vaccination, that person should receive a single revaccination with 15 punctures (jabs) at a separate site. People previously vaccinated, especially if they have received multiple doses, may not respond to smallpox vaccine because of current immunity. Revaccination should not be repeated more than once in the short term. People previously vaccinated who do not respond with a visible skin lesion after two attempts should be considered medically immune. Others should be referred for immunologic evaluation.

(6) Training. Medical commanders will use standardized materials to train smallpox vaccinators. Healthcare providers must be ready to explain the characteristics of smallpox vaccine to our soldiers, patients, family members, and other beneficiaries. Training resources at www.smallpox.army.mil defines training standards for three categories of healthcare providers who will implement the SVP locally. Within this training tool, participants register and specify their levels of expertise. They will then view a menu of

videotaped presentations. Required training and optional training for each provider level will be displayed. Units may use this web-based tool for their personnel to train on-line, or download the presentations and perform classroom-style training. The three categories of healthcare providers involved in local SVP implementation are:

(a) Medical Director. Serves as the subject-matter expert for the installation commander, working for the MTF Commander. The Medical Director is responsible to the MTF Commander for local execution of the SVP, training of Clinical Consultants and Vaccination Supervisors, and training verification and training documentation of all personnel.

(b) Clinical Consultants and Vaccination Supervisors.

1 Clinical consultants will typically be physicians, physician assistants or nurse practitioners who provide clinical services. Clinical consultants will review screening forms before vaccination and either authorize vaccination, grant exemption from vaccination, or refer vaccine candidates for further evaluation. Clinical consultants may provide classroom education of vaccinees before vaccination.

2 Vaccination supervisors will typically be registered nurses or physician assistants. Vaccination supervisors train and document training of vaccinators and provide direct on-site supervision of vaccinations and vaccination-clinic operations. This may include providing classroom education of vaccinees before vaccination. Vaccination supervisors ensure all vaccinees complete the pre-smallpox vaccination screening form.

(c) Vaccinators. Vaccinators administer vaccinations, provide post-vaccination instructions, and assist vaccinees in obtaining additional information.

(7) Quality Assurance. Medical commanders will assess vaccination technique by evaluating the vaccination take rates among the first cohort of people (e.g., 50 to 100) vaccinated by each vaccinator. Recent published studies found take rates > 95% with appropriate technique.

3. MEDICAL RECORD KEEPING.

a. A permanent entry will be made in the individual's health record IAW AR 40-562 after smallpox vaccine is administered. Entry will include the date of vaccination, name of vaccine, manufacturer, lot number, dose and route of administration, site of administration (e.g. right upper arm) and name of healthcare provider involved in vaccine administration. Current versions of PHS Form 731, International Certificates of Immunization, no longer contain dedicated segments to record smallpox vaccination and responses. In such records, vaccination "take" will be documented in individual health records immediately beneath the vaccination entry by writing the date of the assessment and the type of reaction: either 'Major Reaction' or 'Equivocal.'

b. For deployment, use the DD Form 2766 folder, (Adult Preventative and Chronic Care Flow Sheet) to accompany the individual; copies will remain in the individual's health record.

c. Implement quality-control and quality-assurance measures IAW AR 40-68 to ensure the accuracy of these entries. As part of the routine Organization Assessment Program (OAP), MEDCOM Inspector General will perform audits of immunization records for quality-assurance purposes, to assure completeness of data entry and agreement of paper and electronic immunization records.

4. AUTOMATED IMMUNIZATION TRACKING SYSTEM (ITS).

a. All immunizations will be posted and tracked IAW ANNEX J in the Army's automated Immunization Tracking System, the Medical Protection System (MEDPROS), the HQDA standard for tracking all individual medical readiness indicators in the active and reserve components, as well as DoD civilians and contractors. Leaders at all levels can track individual and unit compliance using MEDPROS from their

desktop. Although various local automated health record systems may be used by clinicians as approved by OTSG/MEDCOM for clinical front-end entry, HQDA requires automated feed into MEDPROS. Local systems not automatically feeding into MEDPROS will not be used.

b. Commanders and healthcare providers are responsible to ensure all smallpox immunizations for their assigned personnel are recorded in MEDPROS within 24 hours of the immunization event.

5. PRE-VACCINATION REQUIREMENTS.

a. Commanders and medical staff will ensure that vaccine recipients are provided adequate information on the vaccine, its safety, its benefits, possible adverse events, contraindications, criteria for medical exemptions for recipients and their household contacts, risks to household contacts and vaccination-site care prior to vaccination. Informational brochures will be distributed to all personnel, military and civilian, before receiving this vaccine.

b. Commanders will provide all vaccine recipients with a briefing on smallpox and the vaccination program. The briefing at Appendix 3, ANNEX E, is provided for this purpose. Updated versions of this briefing will be posted at www.smallpox.army.mil. Vaccine recipients will be provided a color picture of the characteristic smallpox vaccination reaction. Recipients will be instructed that they will have a visual inspection of their vaccination site 6-8 days after receiving vaccine. They will also be instructed that if for some reason they are unable to report for take assessment, they must report back to the vaccination clinic if they do not develop a characteristic reaction.

c. Personnel will be given the opportunity to ask questions of healthcare providers prior to vaccination.

d. The national standard of practice for all immunizations, including the smallpox vaccine, shall be adhered to when immunizing personnel. This includes medical screening prior to immunization. Screening shall be conducted for medical conditions for which immunization deferral or further medical evaluation before immunization is indicated.

e. Per AR 600-110, live virus vaccines such as smallpox vaccine may be administered to military personnel provided there is a record of a negative HIV test within the previous 24 months. HIV testing is not mandatory for civilian personnel, but may be performed as indicated by medical screening, and evaluation in a military medical treatment facility for this purpose.

f. Healthcare professionals and staff play key roles in this program, both in its execution as well as providing expert advice to soldiers, civilians, and commanders. They must become familiar with key aspects of smallpox (variola virus) disease and the smallpox (vaccinia) vaccine. All must read the package insert (Ref. G this ANNEX) and be familiar with the informational briefings referenced at Appendices 3 and 4 ANNEX E and the additional resources at Appendices 5 and 6. These will be crucial in communicating to the troops that the vaccine is safe and effective, if used properly. Healthcare providers will remain alert to modifications in clinical recommendations as the SVP continues. Such changes will be posted at http://www.smallpox.army.mil/.

g. Medical personnel must understand the potential adverse events that are possible after smallpox (vaccinia) vaccination. They must know how to minimize them, how to respond to them and report them IAW Part 8 this ANNEX. Medical personnel will not only administer the vaccine, but will likely be the "front line," responding to vaccine recipients' questions and concerns. Medical personnel must treat each concern with care. Some symptoms following smallpox (vaccinia) vaccination may or may not be caused by the vaccination, but all deserve individual attention.

h. Before beginning smallpox vaccinations at any installation, preventive medicine (PM) staff will contact their counterparts at city, county, and state public health departments to inform them that smallpox vaccinations will begin in the near future. PM staff may inform them of a rough order of magnitude of number of vaccinations to be carried out, but need not inform them of unit names or duties.

PM staff may describe staff training procedures, servicemember education, and efforts to prevent auto-inoculation and contact transfer of vaccinia virus to others.

6. MEDICAL EXEMPTIONS FROM SVP.

a. Some individuals will have either acute or chronic pre-existing conditions that may warrant medical exemption from smallpox vaccination. In some cases, vaccination should be withheld if the individual cannot avoid household contact with another person with contraindicating conditions. Furthermore, a small proportion of individuals will develop a more serious reaction that may warrant medical exemptions, temporary or permanent, from further smallpox vaccination.

b. In a smallpox emergency, there are no absolute contraindications regarding vaccination of a person with a high-risk exposure to smallpox. People at greatest risk for experiencing serious vaccination complications are often those at greatest risk for death from smallpox. If a relative contraindication to vaccination exists, the risk for experiencing serious vaccination complications must be individually weighed against the risk for experiencing a potentially fatal smallpox infection.

c. Granting medical exemptions is a medical function only to be performed by a privileged DoD health-care provider (specifically, a physician, physician assistant, nurse practitioner). The provider will grant individual exemptions when medically warranted, with the overall health and welfare of the patient clearly in mind, balancing potential benefits with the risks while taking into consideration the threat situation.

d. The two most common medical exemptions utilized are medical temporary (MT) or medical permanent (MP). Annotate the patient's Health Record and record in the MEDPROS immunization tracking system these codes, and update them as appropriate. In the event of a confirmed smallpox outbreak, permanent exemptions could be lifted, based on individual risk.

e. People who have household contact with a person vulnerable to vaccinia virus (e.g., immune-suppressed people, people with atopic dermatitis or eczema, pregnant women) shall either have alternate housing arrangements or be exempted from smallpox vaccination until the household-contact situation is no longer applicable. Scheduling vaccinations just before or during 21-day deployments or family separation is another option. This avoidance of contact should continue until the vaccination scab falls off on its own. Note that this contact relates to household contacts, not to family members per se. The risk is that of contact transfer of vaccinia virus. In a barracks or similar military setting, the only major concern involves close berthing situations, described below.

f. Military-unique berthing settings require similar precautions. Exempt individuals should be physically separated and exempt from duties that pose the likelihood of contact with potentially infectious materials (e.g., clothing, towels, linen) from recently vaccinated people. This separation will include not having the vaccine recipient share sleeping or close living space (e.g., the same cot, bunk, berth, mattress, sleeping bag) with susceptible people. Close occupational settings (e.g., vehicles, tanks, aircraft) are not affected, if due attention is given to simply covering the vaccination site with Band-Aids and sleeves.

g. Temporary medical exemptions are warranted when a provider has a concern about the safety of continued immunizations. Examples of situations that warrant a temporary medical exemption appear in the vaccine's package insert (e.g., immune-suppressed people, pregnant women). The ACIP notes that people with other acute, chronic, or exfoliative skin conditions (e.g., atopic dermatitis, burns, impetigo, or varicella zoster, herpes, psoriasis, severe or uncontrolled acne) may also be at higher risk for eczema vaccinatum and should not be vaccinated until the condition resolves.

h. In situations where a medical condition is being evaluated or treated, a temporary deferral of smallpox vaccination may be warranted, up to 12 months. This would include significant vaccine-associated adverse events that are being evaluated or while awaiting specialist consultation. The attending physician will determine the deferral interval, based on individual clinical circumstances.

i. Medical permanent (MP) exemptions are generally warranted if the medical condition or adverse reaction is so severe or unremitting that, the risk of subsequent immunization is not justified. In the case of smallpox vaccine, these permanent exemptions could be lifted if the individual had prolonged face-to-face contact with someone in the contagious phases of smallpox. Examples of situations otherwise warranting a permanent medical exemption appear in the vaccine's package insert (e.g., life-threatening allergy to a vaccine component, immune-suppressed people, people infected with human immunodeficiency virus, people with atopic dermatitis or eczema or a past medical diagnosis of eczema). People with contraindicating skin conditions who received smallpox vaccine earlier in life may be revaccinated after medical consultation for individual risk-benefit decision-making.

j. If an individual's clinical case is complex or not readily definable, consult an appropriate medical specialist with vaccine safety assessment expertise, before a permanent medical exemption is granted. In addition, the original health care provider may consult with physicians working with the Vaccine Healthcare Center Network. Medical records will be accurately and appropriately annotated pertaining to any temporary or permanent medical exemptions. When no longer clinically warranted, medical exemptions will be revoked.

k. If a patient disagrees with an initial medical decision or diagnosis, he or she may request a second opinion at the next higher military medical treatment facility. If the second opinion is one with which the patient again disagrees, he, or she may be referred directly to the Vaccine Healthcare Center Network.

l. Each military treatment facility will assist people in obtaining appropriate specialty consultations expeditiously and assist in resolving patient difficulties. Specialists, (who are privileged healthcare providers, specifically a physician, physician assistant, or nurse practitioner) may grant permanent medical exemptions. Return of the patient to his or her DoD primary-care provider is not required if the referring specialist deems a permanent medical exemption is warranted. The following medical exemption codes relate to all vaccines. File a Vaccine Adverse Event Reporting System (VAERS) report for any permanent medical exemption due to a vaccine related adverse event.

m. Medical Exemption Codes.

Code	Meaning	Explanation or Example	Duration
MP	Medical, Permanent*	1. Diseases or conditions that cause immunodeficiency or immunosuppression in vaccinee: e.g., HIV/AIDS, solid organ or stem cell transplant, generalized malignancy, leukemia, lymphoma, agammaglobulinemia. 2. Previous severe allergic reaction to smallpox vaccine or to any vaccine component (polymyxin-B sulfate, dihydrostreptomycin sulfate, chlortetracycline hydrochloride, neomycin sulfate, latex in stopper). 3. People who have ever been diagnosed with eczema or atopic dermatitis. 4. Treatments that cause chronic immunodeficiency or immunosuppression in vaccinee: e.g., treatment with radiation, antimetabolites, alkylating agents, corticosteroids, chemotherapy agents, or organ transplant medications.	Indefinite
MI	Medical, Immune	Evidence of immunity. 1. For clinical smallpox, documented infection (indefinite exemption). 2. Documented confirmed take in medical records within the past 5 years after primary vaccination or 10 years after revaccination.	10 years
MT	Medical, Temporary	1. Age less than 12 months. 2. During pregnancy, suspected pregnancy, or to household contacts of pregnant women. Also during breastfeeding. 3. Hospitalization, convalescent leave, moderate or severe acute illness. 4. Treatments or medical conditions that cause temporary immune suppression. 5. Vaccinee has household or other intimate contact with someone who would personally be exempted from vaccination due to a medical condition. 6. If vaccinee or household contacts have acute, chronic, or exfoliative skin conditions, e.g. wounds, burns, impetigo, chickenpox, shingles, herpes, uncontrolled acne, psoriasis, they are at risk for auto-inoculation and should not be vaccinated until the condition resolves. 7. Any temporary contraindication to immunization.	Specified period
MD	Medical, Declined	Declination of optional vaccines, religious waivers.	Indefinite
MS	Medical, Supply	Exempt due to lack of vaccine supply.	Indefinite
MR	Medical, Reactive	Severe adverse reaction after immunization (e.g., anaphylaxis). Code can be reversed if an alternate form of prophylaxis is available. Always warrants a VAERS report, when case is contemporary and data exists to complete the VAERS report. In the cases where MR exemption is granted and documented based on patient's past medical history of severe adverse reaction to this vaccine, sufficient data may not be available to file a VAERS report.	Indefinite

7. EXPECTED REACTIONS.

a. In a nonimmune person who is not immunosuppressed, the expected response to primary vaccination is the development of a papule at the site of vaccination 2-5 days after administration. The

papule becomes vesicular; the pustule usually reaches it maximum size in 8-10 days. The pustule dries and forms a scab, which separates in 14-21 days after vaccination, leaving a scar.

b. As with any vaccine, some individuals receiving smallpox vaccine will experience side effects or adverse events. Adults vaccinated for the first time may develop a clinical illness with injection-site inflammation, muscle aches, and fatigue, most often on days eight to nine after vaccination. In rare instances, smallpox vaccine exhibits a unique, more severe adverse-event profile including encephalitis, progressive vaccinia, eczema vaccinatum and other conditions.

c. DoD Clinical Guidelines for Management of Adverse Events After Vaccination offer useful advice. These guidelines are available at Refs d, e and h of this ANNEX. Specific guidance for management of adverse reactions unique to smallpox vaccination will be published at a later date.

d. Specific information about treatment with vaccinia immune globulin (VIG) appears in the DoD Smallpox Response Plan and in ACIP recommendations. In summary, VIG is available under investigational new drug (IND) protocol to treat progressive vaccinia, eczema vaccinatum, severe generalized vaccinia and severe ocular vaccinia. Providers may request use of VIG for a named patient by telephoning the U.S. Army Medical Research Institute of Infectious Diseases at 1-888-USA-RIID (1-888-872-7443) 24 hours a day. Additionally, after duty hours, one can call the USAMRIID Security Desk at 301-619-2257, or page the USAMRIID staff duty officer at 301-631-4393. IND-specific procedures must be followed carefully.

8. ADVERSE-EVENT RECORDING AND REPORTING.

a. Document all significant adverse events in the individual's health record. Mandatory information for adverse-event reporting consists of identification of the vaccine, the lot number and manufacturer, the date of administration, the name and location of the medical facility, the type and severity of the event. In addition to recording the event in the health record, all adverse vaccine events resulting in death, hospitalization, or more than 24 hours lost from duty must be reported to the Vaccine Adverse Events Reporting System (VAERS). Reports must also be filed for cases of auto-inoculation or contact transfer. Further, the patient or healthcare provider is encouraged to report other adverse events that in the provider's professional judgment appear to be unexpected in nature and severity. Submission of a VAERS report is not an indictment against the vaccine, vaccine administrator, health care facility, chain of command, or an individual. It simply facilitates review of temporally associated conditions and adds to the safety database on the vaccine.

(1) Medical personnel will submit VAERS reports to the supporting USAMEDCOM MTF. Online reporting to www.vaers.org is encouraged, to facilitate data entry and review by the VAERS staff. Print out copies of these reports to the MTF Pharmacy and Therapeutics Committee for review.

(2) The Chairman, MTF Pharmacy and Therapeutics Committee, will submit reports to the FDA's Vaccine Adverse Event Reporting System, PO Box 1100, Rockville, MD 20849-1100, if not already reported (See ANNEX A, references 2 and 3; Ref. f this ANNEX).

(3) The Chairman, MTF Pharmacy and Therapeutics Committee will also provide a copy of the VAERS report to the Reportable Disease Project Officer at the Army Medical Surveillance Activity (AMSA), U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM), Building T-20, Walter Reed Army Medical Center, Washington, DC 20307-5100, DSN 662-04741 or commercial 202-782-0471. Reportable adverse events will also be reported to AMSA, through the MTF preventive medicine activity, using the automated reportable events system.

(4) VAERS forms are available directly from the Internet at the website referenced at Ref h this ANNEX or can be obtained by calling 1-800-822-7967, Monday – Friday, 0800 – 1700 ET.

(5) A VAERS report should be filed for any permanent medical exemption due to a vaccine-related adverse event.

b. Adverse event reports from National Guard and Army Reserve units will be filed through command channels to the appropriate ARNG State Area Command (STARC) or Army Reserve intermediate headquarters—Reserve Support Command (RSC), 7th Army Reserve Command (7th ARCOM), U.S. Army Special Operations Command (USASOC), or Army Reserve Personnel Command (AR-PERSCOM), as applicable—to the appropriate AMEDD Regional Medical Command (RMC). The RMC will ensure an appropriate Pharmacy and Therapeutics Committee reviews the reports and forwards them IAW Part 8.a.

c. USACHPPM will also receive consolidated adverse event reports from each Service through the Defense Medical Surveillance System (DMSS) and provide quarterly status reports to USAMEDCOM.

9. CONTRAINDICATIONS AND PRECAUTIONS.

a. Contraindications.

(1) Individuals receiving therapy with systemic corticosteroids or immunosuppressive drugs such as alkylating agents, antimetabolites, or radiation, or if household contacts are receiving such therapies.

(2) Immunodeficiency diseases such as AIDS, cancer, agammaglobulinemia, or household contacts of such individuals.

(3) Life-threatening allergies to polymyxin B sulfate, dihydrostreptomycin sulfate, chlortetracycline hydrochloride, neomycin sulfate, or latex (from the stopper).

(4) Individuals of any age with atopic dermatitis or eczema or past history of atopic dermatitis or eczema, or for those whose household contacts have atopic dermatitis or eczema, or acute, chronic, or exfoliative skin conditions, such as atopic dermatitis, wounds, burns, impetigo, varicella zoster, or uncontrolled acne or psoriasis, and for household contacts of such individuals.

(5) Women who are pregnant, or household contacts of pregnant women.

(6) Breast-feeding women.

b. Precautions.

(1) Routine immunization precautions against allergic and anaphylactic reaction should be followed IAW AR 40-562. Personnel with a history of latex sensitivity should be referred for medical advice, because the vial stopper contains dry natural rubber. All personnel should be observed for 15 minutes or longer for any sign of hypersensitivity reaction.

(2) Defer immunization for any person with an active infection with fever. Persons with moderate or severe acute illness should also defer vaccination until recovery (MT).

(3) The vaccine vial, its stopper, the needle to release the vacuum, the diluent's syringe, the vented needle used for reconstitution, the bifurcated needle used for administration, and any gauze or cotton that came in contact with the vaccine should be burned, boiled, or autoclaved before disposal.

(4) Because the risks of smallpox vaccine in HIV infected individuals are not completely known, smallpox vaccine should not be given to HIV infected individuals in routine, non-emergency conditions. There are no data on the safety or effectiveness of smallpox vaccine in HIV-infected individuals.

(5) Vaccinia virus may be cultured from vaccination site 2 to 5 days after vaccination and until scab separates from the skin lesion 14 to 21 days after vaccination. During this time, care must be taken to prevent spread of virus to another area of the body or to another person.

(6) Recently vaccinated healthcare workers should minimize contact with unvaccinated patients, particularly those with immunodeficiencies until the scab falls off. The vaccination site must be well covered and good hand-washing technique is essential by the vaccinee to protect patients.

(7) Pregnancy, Breastfeeding, & Infant Care.

(a) Because the risks of smallpox vaccine in pregnancy are not completely known, smallpox vaccine should not be given to pregnant women in routine, non-emergency conditions. All immunization clinics will display in a prominent place written warning against unintentionally vaccinating pregnant women. This warning must be visible during the screening process. To ensure that pregnant women are not immunized inadvertently, the following procedure will be followed:

1 Before immunization, each woman of child-bearing age will be provided information concerning immunizations and pregnancy. In addition to general information on this topic, specific information on the vaccine will be provided.

2 Provided with this information and the opportunity to read it, each woman will be asked if she is pregnant or could be pregnant.

3 Each woman will be asked if she would like to have a test performed to confirm a possible pregnancy. A urine pregnancy test is sufficient for verification.

4 Each woman and the medical personnel conducting the interview will document the interview by initialing and dating the general information. The sheet will be maintained in the woman's medical record.

5 If the woman states that she is not pregnant or if she is found not to be pregnant on testing, then she will be immunized.

6 If a pregnancy test is requested by the woman, immunization will be deferred until a pregnancy test is completed. If the test is positive, immunization will only be given if clinically indicated.

(b) On rare occasions, almost always after primary vaccination, vaccinia virus has been reported to cause fetal infection. Fetal vaccinia usually results in stillbirth or death of the infant shortly after delivery. Vaccinia vaccine is not known to cause congenital malformations. Any episodes of immunization with smallpox vaccine during pregnancy must be documented in the woman's medical record.

(c) Advise women to avoid pregnancy for 4 weeks after smallpox vaccination, to avoid any hypothetical risk of problems very early in pregnancy.

(d) Breast-feeding (lactation). It is not known whether vaccine antigens or antibodies are excreted in human milk. Breast-feeding may place an infant in close proximity to the mother's vaccination site, increasing the risk of contact transfer of vaccinia virus. The vaccine is not recommended for use in a nursing mother in non-emergency conditions.

(e) People with infants less than 1 year old in the household should be vaccinated only if alternate care-giving arrangements are observed until the scab falls off.

(8) Blood donations. Because there is a significant donor deferral period associated with smallpox vaccination, it is critical that vaccination schedules be closely coordinated with local military and civilian donor center collections schedules to reduce the impact on the readiness and availability of the military blood supply. Individuals who receive the vaccination, and have no complications, will be deferred from donating blood until the scab spontaneously separates (14-21 days after vaccination). In cases where a scab is otherwise removed, the donor may be deferred for two months after vaccination. Individuals with vaccine complications will be deferred until 14 days after all vaccine complications have completely resolved.

10. The points of contact for this ANNEX are as follows:

a. Administrative Issues—MILVAX Agency, 1-877-GET-VACC, http://www.smallpox.army.mil/.

b. Medical Record Keeping Issues—OTSG Health Policy and Services, Patient Administration Division, 703-681-3106, DSN—761-3106.

c. Pre-vaccination Requirements--the Preventive Medicine Staff Officer at Office of The Surgeon General, HQDA, ATTN: DASG-HS-PM, DSN 761.3160; COMM (703) 681-3160.

d. Medical Exemption Issues-- MILVAX Agency, 1-877-GETVACC, http://www.smallpox.army.mil

e. Expected and Unexpected Adverse Events After Vaccination—Walter Reed National Vaccine Healthcare Center, (202) 782-0411, or DSN: 662-0411, http://www.vhcinfo.org/.

f. Adverse Event Recording and Reporting, the Preventive Medicine Staff Officer at Office of The Surgeon General, HQDA, ATTN: DASG-HS-PM, DSN 761.3160; COMM (703) 681-3160.

g. Contraindications and Precautions, MILVAX Agency—1-877-GET-VACC, http://www.smallpox.army.mil/.

APPENDIX 1 to ANNEX C (MEDICAL CONSIDERATIONS AND GUIDANCE)

OPTIONS FOR VACCINATING PERSONNEL OTHERWISE MEDICALLY EXEMPT BECAUSE OF HOUSEHOLD CONTACTS

1. Situation.

a. A person is eligible for smallpox vaccination due to duty assignment and medical history. However, even if the person to be vaccinated may not have a personal medical history contraindicating vaccination (e.g., eczema, immune-suppression, pregnancy) per Annex C, para 6, that person may have a household contact (e.g., spouse, child) who has a medical contraindication related to the vaccinia virus within smallpox vaccine. By DoD clinical policy dated 26 Nov 02 (http://www.smallpox.army.mil/media/pdf/SPclinicalpolicy.pdf):

> "People who have household contact with a person who has a contraindication to smallpox vaccination (e.g., immune-suppressed people, people with atopic dermatitis or eczema, pregnant women) shall either have alternate housing arrangements or be exempted from smallpox vaccination until the household-contact situation is no longer applicable. Scheduling vaccinations shortly before or during 21-day or greater deployments or family separation is an option. This avoidance of contact should continue until the vaccination scab falls off on its own."

b. The hazard to avoid is the spread of vaccinia virus from the vaccination site to another person by inadvertent contact, either directly or by means of clothing, towels, sheets, or similar items that could transfer the virus. Historically, the rate of spread of vaccinia virus to contacts was quite rare, about 27 cases per million vaccinations, mostly in households. But DoD's goal is to reduce the risk as much as possible.

2. Commanders' Responsibility.

a. Commanders will actively manage their personnel who are temporarily medically exempt from smallpox vaccination due to a household contact who has a medical contraindication and ensure their vaccination when that household contact exemption no longer applies. Commanders basically have two options, either (1) arrange for alternate housing from day of vaccination until the vaccination scab falls off (about 14-21 days), or (2) vaccinate the person when the exemption no longer applies (e.g., after family separation during mobilization or at time of deployment).

b. Unacceptable. Permitting a vaccine recipient to reside in a house, trailer, apartment, or similar household with a medically exempt contact is unacceptable, until the scab falls off. Similarly, having a smallpox vaccine recipient share sleeping space (e.g., same cot, bunk, berth, mattress, sleeping bag) with medically exempt people is unacceptable. Close occupational settings (e.g., vehicles, tanks, aircraft) are not affected by these exemptions, if due attention is given to simply covering the vaccination site with Band-Aids® and sleeves.

c. Acceptable.

(1) Vaccinating the person when the exemption no longer applies is acceptable. Commanders can manage their roster of temporary medical exemptions due to household contacts and vaccinate those personnel after family separation, during mobilization or at time of deployment.

(2) Having the vaccinated servicemember use alternate lodging (e.g., barracks, dormitory room, tents) on a military installation, vessel, or aircraft, or in contracted space is acceptable. Funding for contracted space is not available centrally, but must be funded by local commands. This arrangement physically separates the servicemember from the exempted household contact.

(3) Having the vaccine recipient voluntarily arrange for alternate lodging in privately-owned or managed space is acceptable, if the unit commander has a reasonable expectation that the vaccine

recipient will comply with the requirement to not share living space with a medically exempt household contact. For example, a male soldier (family #1) can move in temporarily with another male soldier (family #2) in the home of family #2, while one wife (family #2) moves in with the other wife (family #1) in the home of family #1.

(4) The vaccine recipient can continue to have reasonable access to a medically exempt household contact, so long as the access includes careful hand-washing and does not involve extensive physical contact or contact involving clothing, sheets, towels, or other items likely to transfer vaccinia virus.

(5) Normal barracks situations in which vaccine recipients share living spaces such as common latrines, bedrooms, kitchens, and TV or game rooms is acceptable. Recipients do not typically experience the close day to day physical contact associated with an intimate family situation. Care should be taken, so recipients do not share towels or linens in a barracks situations; they should do their own laundry. Vaccine recipients living in barracks should follow routine site care instructions—simply covering the vaccination site with Band-Aids® and sleeves—to avoid spread of the vaccinia virus.

APPENDIX 2 to ANNEX C (MEDICAL CONSIDERATIONS AND GUIDANCE)

12-STEP APPROACH TO SMALLPOX VACCINATION

1. Space. Plan for:

a. classroom or auditorium space for briefings,

b. smaller, more private space(s) for vaccine candidates to ask questions of clinicians about their personal situation,

c. clinic space for vaccine delivery and documentation. See also Annex B of the DoD Smallpox Response Plan, ANNEX A, Ref 11.

2. Supplies & Logistics. Vaccine kits come with 100 bifurcated needles each. Plan separately for hand sanitizers, cleansing supplies (e.g., soap, acetone, alcohol, disinfectants), 2x2 sterile gauze, 4x4 sterile gauze, 2x3 Telfa gauze, Micropore, Transpore, Scanpore tape, semi-permeable membrane bandages for healthcare workers, standard Band-Aids® for other vaccine recipients, gloves, rigid sharps containers, biohazard bags, extra bifurcated needles for training, tape-glue remover, paper rulers, forms, et cetera.

3. Identify Teams, Team Leaders, & Clear Division Of Responsibilities. Establish methods for communication. Plan regular meetings. Establish email groups to share new information or changes to plan rapidly. Define prescribing authority to administer the vaccine. Identify expeditious pathways for clinical consults (e.g., cell-phone access to dermatologists or other specialists by primary-care providers screening vaccine candidates). Before initiating smallpox vaccinations, flight surgeons should record background rates of "duties not including flying" (DNIF) among aviators, to determine effects of smallpox vaccination on DNIF rates.

4. Train Medical & Support Personnel Thoroughly. Provide smallpox-specific training for medical director, clinical consultants, vaccination supervisors, vaccinators (see education toolkit at www.smallpox.army.mil for training presentations; via CD-ROM in remote locations), administrative team, logistics team, information management team, patient-administration team, laboratory-support team. Agree on scope of practice for each professional and paraprofessional category of worker. Review emergency procedures for fainting, anaphylaxis, other acute events, need for vaccinia immune globulin. Clinicians need to be familiar with DoD clinical policies at: http://www.smallpox.army.mil/media/pdf/SPclinicalpolicy.pdf. Speakers must be well versed in smallpox and vaccinia details (at a minimum, be fluent in the questions and answers at www.smallpox.army.mil, resource center).

5. Public Relations. Notify city, county, and state or host nation health department that vaccinations are about to begin. Prepare press release for local news media. Permit access to knowledgeable spokesperson, but do not allow media to disrupt clinic flow. Media may take photographs of vaccination; however, IAW DoD Public Affairs Guidance **DO NOT** allow photographs that identify the soldier/civilian or unit involved. Coordinate with installation public-affairs outlets (e.g., installation newspaper).

6. Educate Vaccine Candidates & Their Family Members & Close Contacts. Provide briefings on smallpox, smallpox vaccine, risks, benefits, issues regarding site care, and ways to prevent auto-inoculation and contact transfer of vaccinia (use current briefing slides at www.smallpox.army.mil, educational toolkit). Permit ample time to answer questions. Ideally, hold education and medical screening events at least the day before vaccination day, to allow time for questions to be answered. Distribution of current DoD Smallpox Trifold Brochure is required (see www.smallpox.army.mil, educational toolkit); your local medical treatment facility has stocks of these for use. Distribution of CDC's Smallpox Vaccine Information Statement (VIS) is recommended. Thirty-day diary cards are available for use, if desired individually or collectively.

7. Answer Vaccine Candidates' Individual Questions. Expect questions to arise after briefing sessions, after vaccination, up through healing of vaccination sites. Provide ready access to healthcare providers to decipher memories of childhood health conditions.

8. Medical Screening Process. Use current version of DoD standard screening forms ("Initial Medical Notes") at www.smallpox.army.mil, resource center, forms). Two- and three-page versions are available, according to clinic preference. Have physician, physician assistant, or nurse practitioner on site during screening to resolve questions about diagnoses and contraindications (especially regarding eczema and atopic dermatitis), to order medical consults, and to determine fitness for smallpox vaccination. Remind medical personnel to accept an oral history of prior smallpox vaccination, supplemented with records or evidence of an earlier vaccination scar. Presumptive evidence includes birth before 1971 (i.e., 1 year of age in 1972) or military entry before 1990.

9. Vaccination.

a. Deliver all jabs (punctures) as close together in space and time as possible. Educate vaccinators to validate the procedure by immediate inspection of vaccination site, looking for trace bleeding or bleeding beneath the skin (petechiae). Vaccinators should avoid inducing frank bleeding (suggesting excess force). If no evidence of skin-surface break (e.g., trace bleeding, petechiae) within ~20 seconds, revaccinate immediately. Walter Reed Army Medical Center used a skin marker to place four dots in a 1-cm diameter circle, with all jabs placed between these aiming points.

b. At the vaccination station, use a team of two vaccinators who trade off duties. One administers the vaccination jabs, while the other acts as blotter, bandager, and documenter. Have additional staff assure completeness of all forms.

c. Locate the vial of smallpox vaccine toward the back of the vaccination station, so that items are not passed over an open vial. A hole may be carved in a Styrofoam block, to prevent the small vial from being accidentally bumped and spilled. During prolonged vaccination sessions, place the vial on a cooling (but not freezing) tray.

10. Post-Vaccination Care.

a. Remind vaccine recipients of importance of not touching vaccination site and using barriers (e.g., Band-Aids, sleeves) and hand washing to prevent auto-inoculation and contact transfer. Instruct vaccine recipients about expected vaccination response. Instruct them where to return for response evaluation. At "take-check" visits, use common DoD form to evaluate response and identify symptoms after vaccination (current versions are available at www.smallpox.army.mil/resource/forms.asp).

b. Use WHO/CDC definitions for major reaction ("take") and equivocal reactions. See www.smallpox.army.mil/media/pdf/SPclinicalpolicy.pdf or paragraph 2.b.(4), ANNEX C this plan.

c. For healthcare workers: Per DoD policy, each DoD hospital and clinic will establish a bandage-checking station, to evaluation bandage integrity at beginning of each worker's duty shift. Replace bandages when the absorbent pad collects exudate (e.g., every 2 to 3 days). With adequate attention to infection control and bandage assessment, there is no need to furlough medical workers. A restriction on hands-on care in transplantation and oncology wards and neonatal nurseries may be prudent.

11. Adverse Events. Assure primary-care clinics are alert to expected and unexpected adverse events after smallpox vaccination. Fever-malaise-lymphadenopathy syndrome may peak 8 to 12 days after vaccination, with greater incidence among primary vaccinees than after revaccination. Refer patient as needed for diagnosis, treatment and follow-up. Report events to the Vaccine Adverse Events Reporting System (VAERS) that involve hospitalization, loss of duty >24 hours, auto-inoculation, or contact vaccinia transfer. Encourage filing VAERS reports online via www.vaers.org, with paper copies submitted via usual reporting channels.

12. Quality Assurance.

a. Confirm adequacy of screening for people with personal or household contraindications to smallpox vaccination. Track the take rate of the first 50 to 100 people vaccinated by each vaccinator, to assure proper technique. Reinforce instructions for bandages, sleeves, and hand washing, to prevent auto-inoculation and contact transfer of vaccinia virus. Confirm proper vaccine storage and handling. Look for differences in take rate or infection rate with one vial, compared to others.

b. Audit quality of entries into electronic immunization tracking systems (e.g., MEDPROS, AFCITA, SAMS) against paper-based immunization records. Emphasize precision of entry for name of vaccine, date of vaccination, lot #, and provider.

Source: Lessons learned at Walter Reed Army Medical Center, Dec 02 – Jan 03.

ANNEX D - LOGISTICS

1. PURPOSE. To provide the logistics concept of operations for the Smallpox Vaccination Program.

2. GENERAL INFORMATION. The following information on smallpox (vaccinia) vaccine is provided:

a. NSN: 6505-00-903-8173.

b. Nomenclature: Smallpox Vaccine Vaccinia (Dryvax®) full-strength.

c. Unit of Issue: 100-dose vial with diluent, 100 bifurcated needles, and 100 transfer needles.

d. Shelf life: up to 60 days after reconstitution, studies underway may justify longer use after reconstitution. See www.smallpox.army.mil for updates on this topic.

e. Storage: Store product at 2 to 8 degrees C (36 - 46 degrees F). DO NOT FREEZE.

f. Acquisition Advice Code: A

g. Cost: The smallpox vaccine will be provided through USAMMA at no cost to units. Ancillary supplies are the responsibility of the receiving activity (see Part 5 for recommended ancillary supplies). The current contract includes manufacturer distribution to first destination. Transportation will be conducted by a commercial freight forwarder for all destinations.

3. CONCEPT OF OPERATION. Logistics Overview.

a. The U.S. Army Medical Materiel Agency (USAMMA) will coordinate the allocation and distribution of the smallpox vaccine with the Military Vaccine Office.

b. The vaccine is centrally funded by the Program Executive Office for Chemical and Biological Defense (PEOCBD)--formerly Joint Program Office for Biological Defense (JPO-BD). The vaccine is not a Defense Supply Center Philadelphia, stocked item; therefore, requisitions for the vaccine will be submitted off-line to United States Army Medical Materiel Agency (USAMMA). USAMMA has web-based ordering capability (http://www.usamma.army.mil/) Notified units will submit their initial requisition for a 60-90 day supply requirement. Units must make plans for submitting their subsequent requisitions of vaccines at 90-day intervals (with sufficient order ship times).

c. When a requisition for the vaccine has been validated by Services and approved by the Military Vaccine Office, USAMMA will forward the requisition to the Centers for Disease Control and Prevention (CDC) National Pharmaceutical Stockpile (NPS). NPS will distribute smallpox vaccine, in coordination with USAMMA, to the requesting activity.

4. RESPONSIBILITIES.

a. Office of the Surgeon General (OTSG)/U.S. Army Medical Command, Military Vaccine Office.

(1) Oversight for the Smallpox Vaccination Program.

(2) Management of the distribution of vaccine worldwide.

(3) Validation of off-line requisitions from units against the HQDA unit priority lists.

b. U.S. Army Medical Materiel Agency.

(1) Coordinate the release of vaccine with National Pharmaceutical Stockpile.

(a) Number of vials to be released.

(b) Address of ship-to activity (because commercial carriers will be used, street, specific building/room number, POC, and phone number must be provided for each shipment; no PO boxes or APO/FPOs).

(2) Coordinate the receipt of vaccine with the activity.

(3) Provide the activity advanced shipping information.

(4) Provide the activity authorization/release of vaccine for use. If immediate release of vaccine is necessary the receiving activity is required to contact USAMMA and follow "green light/red light" instructions. (Ref. APPENDIX A this ANNEX)

(5) Provide the activities vaccine redistribution instructions for vaccine when required. (Ref. Appendix B)

(6) Provide the activities disposition instructions for vaccine when required. (Ref. APPENDIX C this ANNEX)

c. Installation Medical Supply Activities (IMSAs)/Medical Logistics Battalions.

(1) Receive and forward off-line requisitions (via USAMMA web site) from supported units. Requisitions forwarded to USAMMA will include the following:

(a) Number of vials requested.

(b) Justification (in a secure environment).

(c) Requestor (IMSA) Info: POC, phone number, fax number.

(d) Servicing Regional Medical Command (RMC).

(e) Ship to Address (including building/room number).

(f) Ship to POC Info: POC, phone number, email address, alternate POC, alternate phone number, alternate email address, fax number.

(2) If the IMSA is the ultimate destination:

(a) Establish due in for the vaccine.

(b) Notify USAMMA POC upon receipt of vaccine with the following data:

1 Receipt of vaccine.

2 Number of vials received by lot number.

3 Condition of vaccine.

4 Shipment discrepancies (i.e., incorrect quantity, damaged shipment, etc.), if applicable.

5 Airway bill tracking number for return of temperature monitor(s).

(c) Return the temperature control monitor(s) to USAMMA, 1423 Sultan Drive, Suite 100, Fort Detrick, MD 21702-5001, in provided FEDEX/DHL envelopes.

(d) Once released by USAMMA, vaccine may be administered by immunization personnel.

(3) Maintain records reflecting quantities, lot numbers, and units to which the lots were distributed.

(4) Provide supply status reports to your RMC, Medical Command, or chain of commands as required.

d. If unit is ultimate destination.

(1) Submit requests for vaccine via IMSA/MEDLOG BN. The IMSA/MEDLOG BN will submit off-line requisitions through the USAMMA web site. Requisitions forwarded to USAMMA will include the following:

(a) Number of vials requested.

(b) Justification.

(c) Requestor (IMSA) Info: POC, phone number, fax number.

(d) Servicing Regional Medical Command (RMC).

(e) Ship to Address (including building/room number); Ship to POC Info: POC, phone number, email address, alternate POC, alternate phone number, alternate email address, fax number.

(2) Establish due in for the vaccine.

(3) Notify USAMMA POC upon receipt of vaccine with the following data:

(a) Receipt of Vaccine.

(b) Number of vials received by lot number.

(c) Condition of vaccine.

(d) Shipment discrepancies (i.e., incorrect quantity, damaged shipment, etc.), if applicable.

(e) Airway bill tracking number for return of temperature monitor(s).

(4) Return the temperature control monitor(s) to USAMMA, 1423 Sultan Drive, Suite 100, Fort Detrick, MD 21702-5001, in provided FEDEX/DHL envelopes.

(5) Once released by USAMMA, vaccine may be administered by immunization personnel.

(6) Maintain records reflecting lot numbers and quantities.

(7) Provide supply status reports to your RMC, Medical Command, or chain of command as required.

(8) Submit requisitions for ancillary supplies to IMSA/MEDLOG BN.

(9) Schedule subsequent off-line requisitions of vaccine at 90-day intervals (allow for order-ship time).

5. ANCILLARY SUPPLIES. The following is the preferred list of ancillary supplies for the administration of smallpox vaccine:

NSN	ITEM	U/I
6510-00-786-3736	Cotton, isopropyl (alcohol pad)	100s
6510-00-782-2700	Sponge gauze 2X3 inch (gauze)	
	Gloves	
	Sharps container	

NOTE: It is expected that resuscitative equipment will be in the immediate vicinity where immunizations are administered. A capability to administer immediate first aid and medical care in the event of an anaphylactic or other allergic reaction will exist at all immunization sites per AR 40-562, paragraph 4.4.

6. SUPPORTING EQUIPMENT. (Ref. APPENDIX 4 this ANNEX) For routine distribution operations for all Armed Services, USAMMA DOC funds the following equipment. Services and/or units may purchase additional supporting equipment below to augment local capability with organic funds.

4110-01-459-3690	VaxiCool	$3,335.00	ea
6515-01-475-8145	VaxiPac	$152.62	ea
6850-01-475-8133	VaxiSafe	$6.00	ea
	Endurotherm Box		
	TempTale (temperature monitor)		

7. COORDINATING INSTRUCTIONS. USAMMA POCs listed below will serve as points of contact for questions and/or problems experienced at MTFs relative to the requisitioning, shipment of materiel, and supporting equipment issues. Clinical and policy questions should be addressed to the Military Vaccine Office POC listed below.

a. POCs at USAMMA:

(1) USAMMA Distribution Operations Center (formerly Focused Distribution Management Branch) Comm: (301) 619-4121, 4128, 4411, 4318, 4198, 4320 DSN: 343-4121, 4128, 4411, 4318, 4198, 4320, FAX: 343-4468.

(2) Website: http://www.usamma.army.mil/

(3) Deputy Director, SVP Distribution Operations & USAMMA Pharmacy Consultant Comm: (301) 619-4307 DSN: 343-4307.

b. Implementation Plan/Policy POC at MILVAX Office:

Chief Army Analyst, Comm: (703) 681-2848, DSN: 761-2848.

APPENDIX 1 to ANNEX D (LOGISTICS)

TempTale Monitor

The Distribution Operations Center (DOC) has a system in place for immediately checking the validity of the product(s) and for releasing the product(s). The following procedures apply:

- If shipped product(s) is needed immediately, contact the Distribution Operations Center at Commercial # 301-619-4121/4128/4411/4198/4318/4320, DSN 343, before opening box.
- Upon receipt of the shipment, with a person from the DOC on the phone, open the container and remove the packing materials until you reach the TempTale monitor. Remove the monitor from the box.
- When looking at the face of the TempTale monitor, you will notice two light-emitting diodes (LEDs) recessed towards the bottom of the label. One is a red light and the other is a green light.
- Turn the bottom of the TempTale towards you. You will notice two holes. One hole will have a silver ring around it and the other hole will not.
- While observing the lights on the face of the TempTale monitor, insert a pen in the hole without the silver ring.
- One of the lights will flash at you.
- **If the light is Green.** Your shipment has arrived within its temperature range. At this time the DOC will release the product(s) for immediate use.
- Place the smallpox (vaccinia) vaccine or vaccinia immune globulin (VIG) into proper refrigeration, which is between 2° to 8°C (36° to 46°F). Check refrigerator temperatures at least daily. Cidofovir (Vistide) is stored at controlled room temperature (25°C or 77°F), although refrigeration is acceptable.
- **If the light is Red.** Your shipment did not arrive within its temperature range and you will receive further instructions from the DOC.
- Products are NOT released for use until you get approval from the Distribution Operations Center.
- Return the TempTale and any other material that may be requested, back to the Distribution Operations Center.

If the products are not needed immediately and it is an Outside the Continental United States (OCONUS) location, then all that is needed is a check on the lights on the monitor. The DOC will be notified that shipment has been received and a report will be given on the color of the light. Products will not be released until the DOC receives the TempTale monitor back from recipient and downloads the information.

- **Note: Red and Green light check procedures are designed to validate that the temperature of the product was maintained within acceptable ranges during transport.**

APPENDIX 2 to ANNEX D (LOGISTICS)

REDISTRIBUTION
SMALLPOX VACCINE
STANDARD OPERATING PROCEDURE (SOP)

1. GENERAL INFORMATION

a. PURPOSE: This SOP is intended to establish detailed procedures and effective command and control for redistribution of smallpox vaccine (Dryvax®).

b. OBJECTIVES:

(1) To minimize loss due to expiration by redistribution throughout military organizations.

(2) To ensure proper handling techniques and transportation requirements are established for redistribution of smallpox vaccine.

c. APPLICABILITY: The procedures contained herein are applicable to all military activities receiving smallpox vaccine.

2. SMALLPOX VACCINE INFORMATION: The vaccine and VIG must be refrigerated and maintained at temperatures between 2° and 8° Celsius (36° to 46° Fahrenheit). DO NOT FREEZE. Check refrigerator temperatures at least daily.

3. IDENTIFY VACCINE: Failure to identify products that will not be administered prior to expiration cannot be permitted. Units must review forecasted immunizations to determine if they will be able to administer on-hand vaccine prior to its expiration date. Activities must notify the USAMMA Distribution Operations Center (DOC) at least thirty (30) days before the expiration date to permit the redistribution of the products to a site that can use it before it expires. The DOC must be contacted to coordinate the redistribution of vaccine for any distance that requires greater than 45 minutes traveling time.

4. VACCINE TRANSPORTATION REQUIREMENTS: Routine shipments of the products are accomplished via DoD approved packaging and shipping containers. In the event redistribution of the vaccine becomes necessary and is approved by the DOC and the respective service agency; the approved method of accomplishing redistribution is via the use of the VaxiCool® or VaxiPac®. The VaxiCool® is a commercially procured vaccine refrigeration system the U.S. Army Medical Materiel Agency (USAMMA) purchased for transport and short term storage of vaccines for all redistribution missions. The VaxiPac® is a commercially procured patented phase change material (PCM) container designed to maintain vaccine at the appropriate temperature (2° – 8° Celsius). The Service Medical Logistic Field Operating Agencies (FOAs) should have several containers available to accommodate multiple deliveries. The DOC will provide all guidance and written instructions to the activities losing or gaining vaccine.

5. REDISTRIBUTION PROCEDURES:

a. Activities must report supply status monthly to USAMMA. The report will include receipts, issues, lot numbers, expiration dates, quantities, and storage temperature history. If additional reporting is required, it will be so stipulated by the DOC, USAMMA. Guidance for product redistribution can be obtained from the USAMMA website: http://www.usamma.army.mil/smallpox/index.htm

b. Reports can be phoned or faxed to: DOC, USAMMA, ATTN: Mrs. Bonnie Pereschuk, Mr. David Orgler, Mrs. Kandi Barnhart, Ms. Liz Andrews, Mr. Ruben Gueits, or Mrs. Kitty Reese at DSN 343-4121/4128/4411/4198/4318/4320; or (301) 619-4121/4128/4411/4198/4318/4320, FAX x-4468.

c. Smallpox vaccine requires strict logistical tracking as a critical medical materiel item requiring close control (similar to controlled substances). The DOC will provide the losing activity detailed packing instructions for the VaxiCool® or VaxiPac® container or Endurotherm Box; gaining activities will be provided with a receiving and processing matrix for the transported vaccine.

d. An empty VaxiCool® or VaxiPac® container or Endurotherm Box with shipping labels and a serial numbered security seal will be sent to the losing activity. If the container is damaged, refuse receipt and notify DOC immediately with details of refusal.

e. If container is in satisfactory condition, receive and process documents and pack vaccine/products in accordance with instructions provided.

f. With the provided pre-addressed, overnight express-mail label, send the VaxiCool® or VaxiPac® to the gaining unit.

g. Call DOC to confirm overnight express-mail airbill tracking number, and security seal serial number for the shipment.

h. Upon receipt of the vaccine the gaining activity will immediately inspect the VaxiCool® or VaxiPac®, security seal for serial number accuracy and contents for damage. If container contains a TempTale monitor, please confirm with DOC for procedures.

i. If container or contents are damaged, refuse shipment and notify the DOC immediately with details.

j. If container is in satisfactory condition, receive and immediately secure smallpox vaccine in the required refrigerated storage environment (2° to 8° Celsius or 36° to 46° Fahrenheit). **DO NOT FREEZE.** Call DOC to confirm receipt.

k. Process documents and vaccine in accordance with the information provided.

l. **Request commercial carrier to wait for the VaxiCool® or VaxiPac®.** Ship container back to DOC using the provided pre-addressed, overnight, express-mail label.

m. Call DOC to confirm overnight express-mail label tracking number.

n. Establish stock record accountability of product IAW Service regulations.

o. **DO NOT RELEASE THE VACCINE TO END-USER UNTIL AUTHORIZED BY THE DOC.**

6. Points of Contact:

ARMY (Executive Agent)/COAST GUARD
USAMMA Distribution Operations Center (DOC)
DSN 343-4121/4128/4411/4198/4318/4320 or (301) 619-4121/4128/4411/4198/4318/4320
FAX x4468
Bonnie.Pereschuk@amedd.army.mil

AIR FORCE
MSGT (S) Dale Clark:
DSN 343-4172 or (301) 619-4172 or
PAGER (888) 587-9892, FAX x2557
Dale.Clark@Ft-Detrick.af.mil

NAVY and MARINE CORPS
HM1 Victor Inniss

DSN 343-7117 or (301) 619-7117
veinniss@us.med.navy.mil

APPENDIX 3 to ANNEX D (LOGISTICS)

DISPOSITION INSTRUCTIONS FOR SMALLPOX PRODUCTS

1. PURPOSE: To provide guidance and procedures for the proper disposition of compromised or expired smallpox vaccine and the preparation of the Executive Summary and DA Form 3161.

2. REFERENCE: Hazardous and Medical Waste Program, U.S. Army Center for Health Promotion and Preventive Medicine, Aberdeen Proving Ground, MD (USACHPPM), and Military Item Disposal Instructions (MIDI).

3. APPLICABILITY: The procedures contained herein are applicable to all DoD activities receiving any product issued under the DoD Smallpox Response Plan or DoD Smallpox Preparedness and Vaccination Program Implementation Plan.

4. EXECUTIVE SUMMARY (EXSUM) PROCEDURES: DoD Activities are responsible for reporting any loss of smallpox product(s), due to expiration, or loss of efficacy by another means, i.e. exceeding required temperature parameters.

The following EXSUM requirements must be reported in memorandum format:

a. DoD activity will prepare the EXSUM within 24 hours upon discovery of compromised vaccine.

b. No longer than one page in length.

c. Explain the circumstances surrounding the loss of vaccine potency or why the activity did not use the vaccine.

d. Complete list of lot number(s).

e. Complete count of whole vial(s).

f. Detailed explanation of course of corrective action to preclude future losses of vaccine/products.

g. List of names and telephone numbers of points of contacts.

The EXSUM should be faxed to the UNITED STATES ARMY MEDICAL MATERIEL AGENCY (USAMMA) Distribution Operations Center (DOC) at 301-619-4468 (DSN 343-4468). **The DOC must receive an EXSUM before replacement vaccine products will be shipped.**

5. DISPOSAL PROCEDURES: Contact the DOC before destruction of any product issued under the DoD Smallpox Response Plan or DoD Smallpox Preparedness and Vaccination Program Implementation Plan. Smallpox vaccine must be handled as infectious waste. **DO NOT DISCHARGE THIS ITEM INTO A SANITARY SEWER.**

a. Activities will report vaccine inventories on-hand to be destroyed to their respective logistic agencies. The report will include information regarding lot numbers and quantities.

b. Activities must prepare a DA Form 3161, Request for Issue or Turn-In, to document disposal actions and fax a copy within 24 hours after final disposition to the DOC at 301-619-4468 (DSN 343-4468). The disposal code for items 6505-00-903-8173 (Dryvax, full strength), 6505-01-499-9118 (Dryvax, diluted 1:5), or 6505-01-053-2600 (Vaccinia Immune Globulin, intramuscular) is CA01. The disposal code for Cidofovir (Vistide) (NDC #61958-0101-01) is AC01.

c. EXSUM and DA Form 3161 should be sent to:

USAMMA Distribution Operations Center (DOC)
DSN 343-4121/4318/4411/4198/4320/4128
COMM: (301) 619-4121/4318/4411/4198/4320/4128
*FAX: DSN 343-4468 COMM: 301-619-4468
Bonnie.Pereschuk@det.amedd.army.mil

6. METHODS FOR DISPOSAL: Explanations for disposal are detailed in the following MIDI Websites:
http://chppm-www.apgea.army.mil/newmidi/longview.aspx?param=CA01
http://chppm-www.apgea.army.mil/newmidi/longview.aspx?param=AC01

The following procedures are in place in the event the above mentioned disposal methods are not available or immediate disposal is necessary:

a. Contact the DOC and provide information regarding lot numbers and quantities. The DOC will provide further shipping guidance.

b. Remove each vial from its package.

c. Tear or shred the insert and package and dispose of as regular waste.

d. Deface the label on each vial with red permanent marker.

e. The activity will pack the container according to instructions provided and mail the container to DOC.

f. The activity will call the USAMMA, DOC, and provide overnight express-mail tracking number for the container.

7. QUESTIONS OR CONCERNS: Personnel responsible for the disposal and destruction should address all questions or concerns to USAMMA at DSN 343-4307/4309 or (301)-619-4307/4309, FAX x4189.

Changes or updates to this SOP must be brought to the attention of the Distribution Operations Center (DOC), UNITED STATES ARMY MEDICAL MATERIEL AGENCY (USAMMA).

APPENDIX 4 to ANNEX D (LOGISTICS)

Equipment

The U.S. Army Medical Materiel Agency (USAMMA) has been tasked with the responsibility for worldwide distribution of the smallpox vaccine for the Department of Defense (DoD). These products must be maintained within controlled temperature limits while in transit. Exceeding these temperature limits could result in loss of product potency. The following containers are currently in use in support of the Smallpox Vaccination Program (SVP):

The VaxiCool: Is a commercially procured, high-efficiency refrigerator system designed for the local transport and/or temporary storage of smallpox vaccine, vaccinia immune globulin (VIG), and other temperature-sensitive pharmaceuticals.

----Manufacturer: Energy Storage Technologies (EST), Dayton, OH
----Model: VX30PPNR
----NSN: 4110-01-459-3690
----Material: It is comprised of Vacupanel Insulation designed to maintain vaccine at 2° - 8° Celsius
----Payload: 400 vials maximum
----Alternate Power sources: 110 AC (220 w/special cable), car battery, solar panels, and car cigarette lighter
----Batteries: 2-12 volt/12 or 14 Amp gel cell batteries
----Total Purchased: 112
----Price: $3,335 ea

The VaxiCool can maintain temperature after being disconnected from a power source for up to 4 days on internal batteries and 16-24 hours more based on its insulation capabilities.

The VaxiPac: The VaxiPac is a small, commercially procured, high-efficiency insulated container used for transport of the smallpox vaccine, VIG, and other temperature-sensitive pharmaceuticals. It uses a product called VaxiSafe to maintain temperature. The VaxiSafe is composed of a Phase Change Material (PCM) that hardens at 6° Celsius and protects against varying temperatures. The VaxiPac comes with 5 VaxiSafes from the manufacturer.

----Manufacturer: Energy Storage Technologies (EST), Dayton, OH
----NSN: 6515-01-475-8145
----Material: It is comprised of Vacupanel Insulation
----Payload: 1 to 24 vials maximum
----Total Purchased: 300
----Price: $152.62 ea
----VaxiSafe Price: $6.00 ea

The VaxiPac is used for re-distributions for up to 24 hours.

Endurotherm Boxes: A complete packing system designed to ensure the cold chain is not broken. They are available in three different sizes: small, medium, and large. Vaccine is shipped from the National Pharmaceutical Stockpile using Endurotherm boxes, which have gone through various testing protocols. This box can maintain the required temperature for up to 7 days.

-----Manufacturer: Insulated Shipping Container (ISC), Inc., Phoenix, AZ

-----Material: It is comprised of two corrugated layers injected with polyurethane foam within a mold. The end product is a rigid, one piece, three layer laminate container.

-----Payload, weight, and contents prices:

- Small Box: 1-20 vials; packed wt - 15 lbs, contains (6) 24 oz Gel packs, (1) small box insert, packing peanuts, tape, labels, (1) cardboard separator and (1) TempTale = $59.00

- Medium Box: 53-110 vials; packed wt - 25 lbs, contains (9) 24 oz Gel packs, (1) large box insert, packing peanuts, tape, labels, (1) large cardboard separator and (1) TempTale - $64.32

- Large Box: 440 vials; packed wt - 75 lbs, contains (13) 24 oz Gel packs, (4) large box inserts, packing peanuts, tape, labels, (1) large cardboard separator and (1) TempTale = $95.70

ANNEX E – EDUCATION/COMMUNICATIONS PLAN

1. GENERAL. The Department of Defense will begin the Smallpox Vaccination Program (SVP), in accordance with FDA guidelines and consistent with the best practice of medicine.

2. OBJECTIVE. Ensure full understanding and acceptance of the Smallpox Vaccination Program by soldiers, DA civilians, their families, Congress, the American public, and the media.

3. GOALS.

a. Inform all stakeholders that to immunize U.S. forces using smallpox vaccine is the right thing to do to best protect selected personnel at greatest risk, and to preserve certain mission critical capabilities against smallpox.

b. Gain soldier, employee, family member, Congressional, public, and media support for the vaccination of U.S. forces against smallpox.

c. Use this opportunity to inform the American public that biological warfare is a potential threat to our forces.

4. KEY MESSAGES.

a. SMALLPOX WOULD DISRUPT MILITARY MISSIONS, BECAUSE IT IS CONTAGIOUS AND DEADLY.

(1) Disruptive. A smallpox outbreak would significantly affect military readiness.

(2) Contagious. Smallpox is a contagious disease that spreads from one person to another.

(3) Dangerous. Before smallpox was eradicated it killed many millions of people over hundreds of years.

b. SMALLPOX VACCINE PREVENTS SMALLPOX, AND WE WILL USE IT VERY CAREFULLY.

(1) Efficacy. The World Health Organization (WHO) used smallpox vaccine to eradicate natural smallpox from the planet.

(2) Expected Effects and Side Effects. All vaccines cause side effects, but smallpox vaccine causes a unique reaction at the vaccination site.

(3) Care of the Vaccination Site. Smallpox vaccination leaves vaccine virus on the surface of the skin, so you have to be careful not to touch the smallpox vaccination site. You don't want to spread the virus somewhere else.

(4) Side Effects--Serious. Very rarely, smallpox vaccine can cause serious side effects.

(5) Exemptions to Vaccination. Some people should not get smallpox vaccine, except in an outbreak.

(6) Smallpox Vaccine. The Defense Department will use smallpox vaccine licensed by the Food & Drug Administration (FDA).

c. PRESERVING THE HEALTH AND SAFETY OF OUR PEOPLE IS OUR TOP CONCERN.

(1) Healthy troops complete their missions. Vaccines will keep you and your team healthy.

(2) Vaccines have kept troops healthy since the days of George Washington.

(3) Vaccination offers a layer of protection that adds to other measures used to protect certain members of the Armed Forces.

d. SMALLPOX PROTECTION HELPS OUR WAR ON TERRORISM: NEW THREATS REQUIRE NEW MEASURES OF FORCE PROTECTION.

(1) The Defense Department is working with other federal departments to strengthen America's defenses against smallpox.

(2) The government has been preparing for years for the remote possibility of an outbreak of smallpox as an act of terror.

5. CONCERNS.

a. The DoD knows that service members, civilian employees, friends and family, and the American public have concerns about the safety of smallpox vaccination and the lethality of smallpox infection. The following list is an example of concerns from individuals:

(1) The threat: Individuals have questioned the validity and the relevance of the threat (how likely is it that a potential adversary will use these weapons--Is the SVP necessary?)

(2) People have general and specific questions about the safety of the vaccine, especially, the potential side effects, including scarring, encephalitis, and death.

(3) It is important to give correct information to people first. Many times people research information on their own and base decisions and beliefs on what they've heard from others (e.g., internet rumors, urban legends, media) instead of scientific, verifiable facts.

(4) Leaders want good, clear guidance on how to execute the program correctly.

6. CONCEPT OF OPERATION.

a. Education.

(1) Before vaccination, Commanders and supervisors will ensure that vaccine recipients are provided adequate and accurate information on the threat, the vaccine, its safety, its benefits, and site care instructions. Commanders and supervisors will provide all vaccine recipients with a briefing on smallpox and the vaccination program. Your local medical treatment facility maintains stocks of educational trifolds for use. All approved educational material is always available on the web www.smallpox.army.mil.

(2) Commanders are encouraged to provide education for family members of soldiers and civilians receiving smallpox vaccinations. For example, this can be accomplished through family support group meetings at unit level and town hall meetings at installation level.

(3) Healthcare professionals and staff play key roles in this program, both in its execution as well as providing expert advice to soldiers and commanders. They must become familiar with all aspects of smallpox (disease and vaccine).

(4) Commanders should coordinate educational meetings and briefings to ensure full participation by healthcare subject matter experts (SME) and PAO staff.

(5) You can get more information on all aspects of the Smallpox Vaccination Program at the official SVP website, www.smallpox.army.mil. You can also call the SVP toll-free information line at 1-

877-GET-VACC, which is staffed Monday through Friday, 0800-1800 Eastern Standard Time. You can send email inquiries to vaccines@amedd.army.mil.

b. Public Affairs. Public Affairs Offices Army-wide will use informational products developed and designed by OTSG/MEDCOM's Military Vaccine Agency (MILVAX) and approved by DoD to garner internal (Army) and external support of the SVP. All products are available on the DoD Smallpox Vaccination Program Website: www.smallpox.army.mil. DoD provided worldwide Public Affairs Guidance by SECDEF Unclassified Message, 131700Z Dec 02, subject: Public Affairs Guidance (PAG) on the Smallpox Vaccination Program.

c. Responsibilities

(1) Army Commanders:

(a) Oversee coordination and execution of this plan.

(b) Identify spokespersons and points of contact at all levels of command for soldiers, employees, family members, and media.

(c) Ensure vaccinees and family members of vaccinees are briefed on local vaccination plans—coordinate with local hospital commander for medical expert assistance.

(d) Ensure these efforts are coordinated with local medical treatment facility commanders or their representatives.

(e) Ensure these efforts are coordinated with local public affairs officers.

(f) Ensure these efforts are coordinated with local judge advocate or legal advisors.

(2) Army Medical Treatment Facility Commanders:

(a) Coordinate with local commanders the medical aspects of the education/communications plan. Maintain stocks of printed trifolds for local commanders' use in educating their personnel. Trifolds can be printed directly from the web, www.smallpox.army.mil; ordered through OTSG/MEDCOM Military Vaccine Agency, 1-877-GETVACC (staffed Monday through Friday, 0800-1800 Eastern Standard Time); or by sending an email to vaccines@amedd.army.mil.

(b) Ensure medical personnel receive the health care providers briefing (Appendix 4) and have access to the clinical questions and answers (Appendix 6).

(c) Ensure local medical personnel are briefed on local vaccine implementation plans.

(d) Identify a medical subject matter expert to participate in interviews with local and civilian media.

(e) Identify a medical subject matter expert(s) to provide or assist with briefings to soldiers, civilian employees, and family support groups.

(f) Identify a medical subject matter expert or office by name and phone number to be included on all soldier, family member, and civilian educational material.

(3) MACOM Public Affairs Officers. Use questions and answers referenced in Appendix 6 this ANNEX, and DoD issued PAG message to respond to media inquiries. Media inquiries not covered in existing DoD guidance should be referred to Jim Turner at james.turner@osd.mil, (703) 697-5132, DSN 227-5135.

APPENDIX 1 to ANNEX E—(EDUCATION/COMMUNICATIONS PLAN)

TRIFOLD INFORMATIONAL BROCHURE

http://www.smallpox.army.mil/media/pdf/spTrifold.pdf

APPENDIX 2 to ANNEX E—(EDUCATION/COMMUNICATIONS PLAN)

SMALLPOX VACCINE INFORMATION STATEMENT FROM THE CDC

http://www.cdc.gov/nip/publications/VIS/vis-spox.pdf

APPENDIX 3 to ANNEX E (EDUCATION/COMMUNICATION PLAN)

INDIVIDUAL'S BRIEFING

http://www.smallpox.army.mil/media/pdf/spINDBrief.ppt

APPENDIX 4 to ANNEX E (EDUCATION/COMMUNICATIONS PLAN)

HEALTHCARE PROVIDER'S BRIEFING

http://www.smallpox.army.mil/media/pdf/spHCPBrief.ppt

APPENDIX 5 to ANNEX E (EDUCATION/COMMUNICATIONS PLAN)

CDC TRAINING REGARDING NORMAL AND UNUSUAL RESPONSES TO SMALLPOX VACCINATION

http://www.bt.cdc.gov/training/smallpoxvaccine/reactions/normal.html

APPENDIX 6 to ANNEX E (EDUCATION/COMMUNICATIONS PLAN)

QUESTIONS & ANSWERS

http://www.smallpox.army.mil/media/pdf/SPQ&A.pdf

ANNEX F - PERSONNEL

1. SCOPE. This ANNEX applies to all members of the active Army, the Army National Guard (ARNG), and the U.S. Army Reserve (USAR).

2. PURPOSE. To provide the personnel concept of operations and assign responsibility for the implementation of the Army's Smallpox Vaccination Program (SVP).

3. REFERENCES.

a. DoD Directive 6205.3, DoD Immunization Program for Biological Warfare Defense, 26 Nov 93.
- http://www.dtic.mil/whs/directives/corres/pdf/d62053_112693/d62053p.pdf

b. AR 40-562, Immunizations and Chemoprophylaxis, 1 Nov 95.
- http://www.usapa.army.mil/pdffiles/r40_562.pdf

c. AR 220-1, Unit Status Reporting, 15 Nov 01.
- http://www.usapa.army.mil/pdffiles/r220_1.pdf

d. AR 600-8 Military Personnel Management, 1 Oct 89.
- http://www.usapa.army.mil/pdffiles/r600_8.pdf

e. AR 600-8-11, Reassignment, 1 Oct 90.
- http://www.usapa.army.mil/pdffiles/r600_8_11.pdf

f. AR 600-8-101, Personnel Processing (In-and Out-and Mobilization Processing), 1 Mar 97.
- http://www.usapa.army.mil/pdffiles/r600_8_101.pdf

g. AR 600-8-104, Military Personnel Information Management/Records, 27 Apr 92.
- http://www.usapa.army.mil/pdffiles/r600_8_104.pdf

h. AR 600-8-105, Military Orders, 28 Oct 94.
- http://www.usapa.army.mil/pdffiles/r600_8_105.pdf

i. AR 614-6, Permanent Change of Station Policy, 7 Oct 85.
- http://www.usapa.army.mil/pdffiles/r614_6.pdf

j. AR 614-30, Overseas Service, 30 Aug 01.
- http://www.usapa.army.mil/pdffiles/r614_30.pdf

k. DA PAM 600-8, Management and Administration Procedures, 1 Aug 86.
- http://www.usapa.army.mil/pdffiles/p600_8.pdf

l. Under Secretary of Defense (Personnel and Readiness) memorandum, Policy on Administrative Issues Related to the Smallpox Vaccination Program (SVP).
- www.smallpox.army.mil

4. CONCEPT OF OPERATIONS. The Army will implement a phased program to vaccinate members of the Active Army and Reserve Components in accordance with the FDA-approved vaccination schedule and OSD and JCS guidance. This ANNEX delineates responsibilities and establishes personnel policy guidance for the establishment of personnel regulatory and procedural directives.

5. PLANNING ASSUMPTIONS.

a. OTSG administers the Medical Protection System (MEDPROS) automated immunization tracking system to track smallpox immunizations.

b. Interim personnel regulatory changes and policy guidance will be approved and published prior to immunizing the force.

c. Personnel record keeping and movement processing will incorporate administrative redundancies to ensure accurate tracking during movement.

d. The MOS/Medical Retention Board (MMRB) and Medical Evaluation Board (MEB) system will establish assignment limitations in conjunction with medical authority.

e. Commanders will submit requests for exceptions through MACOMs to HQDA, Office of The Surgeon General, Military Vaccine Office, 5109 Leesburg Pike, Falls Church, VA 22041 for approval and coordination with gaining Combatant Command, CJCS and ASD (HA).

6. RESPONSIBILITIES.

a. Deputy Chief of Staff for Personnel, G-1.

(1) Coordinate with U.S. Military Entrance Processing Command (USMEPCOM) all personnel policies pertaining to pre-accession considerations concerning smallpox immunizations.

(2) Observe medical guidelines established by the Surgeon General in ANNEX C when originating personnel vaccination directives.

b. Deputy Chief of Staff for Operations, G-3.

(1) In conjunction with the Deputy Chief of Staff for Personnel, update procedures for readiness reporting which incorporates unit smallpox immunization status.

(2) Establish and/or validate priorities for units and personnel to receive the smallpox vaccine.

c. The Surgeon General.

(1) Advise G-1, G-3, and the Office of the Assistant Secretary of the Army, (Manpower, and Reserve Affairs) on all clinical policy decisions that impact personnel and readiness regulations. Clinical policy must be set prior to incorporation of new personnel policy into existing regulations.

(2) Ensure personnel exhibiting adverse events after smallpox (vaccinia) vaccination are properly profiled. Establish clinical guidelines and establish profile policy for clinicians.

(3) Establish appropriate physician profiles for soldiers experiencing adverse events after smallpox immunizations that preclude further vaccination.

(4) Establish medical policies and implement procedures that delineate populations for which smallpox immunizations are medically contraindicated or not required. Select individuals are exempt from smallpox immunizations and therefore utilization policies must be considered.

d. Commander, Total Army Personnel Command (PERSCOM).

(1) Establish regulatory policy and procedural requirements to ensure smallpox immunization status is properly documented in orders prior to movement of personnel.

(2) Establish in- and out-processing controls that cause soldiers on assignment instructions to designated areas to complete smallpox immunizations prior to permanent change of station.

(3) Incorporate smallpox immunization requirements and documentation into all Soldier Readiness Processing (SRP) regulatory guidance.

e. Chief, National Guard Bureau (NGB).

(1) Advise G-1 regarding the impact of the SVP on National Guard personnel and units.

(2) Develop and coordinate National Guard smallpox immunization policy for State Area Commands and the Air National Guard.

(3) Develop policy and procedures for documenting smallpox vaccination response and immunization adverse event medical profiles in personnel and medical records so they can be used for readiness and mobilization processing.

(4) Establish a business process to monitor the incidents of adverse event that occur after the soldier has been released from military control (i.e. annual training, BCT, AIT).

f. Chief, Army Reserves (CAR).

(1) Advise G-1 regarding the impact of the SVP on USAR personnel and units.

(2) Develop and coordinate USAR smallpox immunization policy for major commands, and the U.S. Army Reserve Personnel Command (AR-PERSCOM).

(3) Develop policy and procedures for documenting smallpox vaccination response and immunization adverse event medical profiles in personnel and medical records so they can be used for readiness and mobilization processing.

(4) Establish a business process to monitor the incidents of adverse event that occur after the soldier has been released from military control (i.e. after annual training, BCT, AIT).

ANNEX G - ARMY NATIONAL GUARD

1. PURPOSE. Provide the Army National Guard (ARNG) concept of operations and planning guidance to the States and Territories for implementing the Smallpox Vaccination Program (SVP).

2. SCOPE. This ANNEX applies to all members of the Army National Guard.

3. Planning assumptions:

a. ARNG soldiers participating in designated areas such as homeland security missions and/or units likely to deploy in support of specific theater of operation where the threat of smallpox is likely, may be vaccinated.

b. All other ARNG soldiers will be placed into the appropriate Priority Category upon notification/selection for selection in an operation located within a designated area.

c. The DA Plan and this ANNEX allow maximum flexibility to the states to use internal and external resources.

d. The Weapons of Mass Destruction (WMD) - Civil Support Teams (CST) will respond to terrorist threats that will require early immunizations of CST team members (Stage 1a).

e. The immunization status of each ARNG member will be tracked by the State Area Command (STARC) using the DA approved tracking system at ANNEX J (MEDPROS). The system will interface and update DEERS.

f. The smallpox vaccine will continue to be the requirement throughout the period of implementation unless notified of an FDA-approved change.

g. DoD will fund additional expenses associated with administration of this program. These costs include, but are not limited to the following: contracts, ancillary supplies, shipping, man-days/per diem/travel for additional training assemblies required for soldiers administering the program and for those receiving the injections, and may qualify for incapacitation pay for treatment of those having adverse reactions.

h. The ARNG will have access to any contracted resources and funding to contract resources to administer the vaccine.

4. RESPONSIBILITIES.

a. G1 Chief, Human Resources Division.

(1) Develop and coordinate the SVP for ARNG.

(2) Ensure the procurement of vaccine and ancillary supplies required to implement the Smallpox Vaccination Program within the National Guard.

b. The ARNG Program Analysis, and Evaluation Division (NGB-ARA). Develop requirements for submission to appropriate Program Evaluation Group (PEG) for the purpose of competing in the Program Objective Memorandum (POM) process.

c. The ARNG Information Management Division (NGB-AIS). Ensure adequate communication support for tracking mechanisms.

d. The ARNG Policy and Communications Office (NGB-ARZ-PC). Develop a public affairs plan in coordination with DoD, DA, and NGB-PA.

e. The ARNG Surgeon's Office (NGB-ARS). Provide related medical policy and guidance.

f. State TAG will:

(1) Ensure ARNG personnel are immunized against smallpox IAW Army guidance.

(2) Develop State plan for implementation of SVP.

(3) Track unit immunization status and provide reports as required.

g. State Area Command (STARC) Medical Detachment will coordinate:

(1) Immunizations in support of state plan.

(2) Annotation of immunizations, including smallpox vaccination response, in the Health Record and the Army's automated immunization tracking system (MEDPROS) IAW ANNEX J.

(3) Commanders' requirements for patient education support.

(4) Adverse event reporting.

(5) Requisition required vaccine and ancillary supplies IAW overall Army plan.

5. CONCEPT OF OPERATIONS.

a. Implementation. The ARNG will implement the SVP IAW priorities established by the Office of the Secretary of Defense (OSD) and the Joint Chiefs of Staff. Reserve Component personnel shall be in a duty status when receiving a DoD directed immunization. Additional guidance on ARNG Program Implementation will be published for the states as an "All States Log Memorandum."

b. Method of Immunization. Implementation of the immunization plan will be based on the state plan to be administered by the STARC Medical Detachment. Resources to vaccinate personnel/units may be used as appropriately coordinated, to include organic medical assets, active component facilities, public health service, or VA medical assets, or private sector contractor. The plan will include processes to evaluate smallpox vaccination responses.

c. Record Keeping. Immunization will be noted in Public Health Service Form PHS 731 (International Certificate of Vaccinations), the Soldier's Health Record, and MEDPROS.

d. Tracking System. Immunizations will be entered into MEDPROS IAW ANNEX J. In anticipation of mass immunizations and mandatory automated tracking, the STARC will identify all personnel requiring access to the automated tracking system, ensure they meet access requirements, and determine the data access level.

e. Logistics. On execution, USP&FO will be responsible for initiating requests for vaccine IAW ANNEX D. USAMMA will direct the distribution of the vaccine and ancillary supplies, as applicable, to the sites designated in the request.

f. Adverse Events. Commanders will establish a mechanism to monitor incidents of adverse event, to include those that occur after the soldier has been released from military control, IAW ANNEX C. National Guard members who experience adverse events and are seeking health services outside of a Military Treatment Facility must contact the Military Medical Support Office (MMSO) at 1-888-647-6676 for guidance.

g. PAO Information. Commanders at all levels will support an aggressive command information program in support of the SVP IAW ANNEX E.

h. Command Responsibility. The execution of the SVP is a command responsibility. The Adjutants General and Commanders at all levels will coordinate with supporting medical activities to ensure that soldiers receive required immunizations.

6. POC: ARNG- Health Care Operations Officer DSN 327-9066 or comm. 703-607-9066.

ANNEX H - U.S. ARMY RESERVE

1. PURPOSE: This ANNEX defines the application of the concept of operations from the basic Smallpox Vaccination Program (SVP) Plan to the U.S. Army Reserve (USAR).

2. SCOPE: This ANNEX applies to all members of the USAR.

3. CONCEPT OF OPERATIONS:

a. Upon order of HQDA, USAR personnel will begin implementation of the SVP. The following USAR organizations will establish policies and procedures governing administration of the SVP for their designated soldier populations per Part 3.a. of the basic plan and ANNEX F.

(1) USARC for CONUS and Puerto Rico based Troop Program Unit (TPU) soldiers under its command and control.

(2) United States Army Europe (USAREUR) and 7th Army Reserve Command (7th ARCOM) for soldiers in their Area of Responsibility (AOR).

(3) United States Army Pacific (USARPAC) and 9th Regional Support Command (9th RSC) for soldiers in their AOR.

(4) US Army Special Operations Command (USASOC) for assigned USAR TPU and Individual Mobilization Augmentee (IMA) soldiers.

(5) U.S. Army Reserve Personnel Command (AR-PERSCOM) for IMA (other than USASOC) and Individual Ready Reserve (IRR) soldiers.

b. Commanders will schedule immunizations in compliance with the FDA vaccination protocol while avoiding training disruptions.

(1) Planning factors for scheduling immunizations should include training and mobilization requirements, allowing sufficient time to administer the immunization and record the effectiveness of the inoculation, and administration of other immunizations IAW sound medical judgment. There is no need to defer this or other immunization until mobilization unless medically contraindicated.

(2) Maximum coordination with other active, USAR, and ARNG commands at the regional level – i.e. Regional Support Commands (RSCs), State Area Command (STARC), and Regional Medical Commands (RMCs) – is encouraged to produce economies of scale and minimize disruption to training.

(3) Reserve component personnel must be in a duty status when receiving a DoD-directed immunization.

c. Command responsibility. The execution of the SVP is a command responsibility. USAR Commanders at all levels will coordinate with supporting activities to ensure that soldiers receive the required immunization per the schedule outlined in the basic plan.

d. Method of immunization.

(1) The primary method of delivery for smallpox vaccine will be by contract provider via the Federal Strategic Health Alliance (FEDS_HEAL) program. FEDS_HEAL providers include the Department of Health and Human Services Division of Federal Occupational Health (FOH), Department of Veterans Affairs (VA) medical assets, and subcontracted civilian providers. Other resources may be used as appropriately coordinated, to include organic medical assets and active component facilities of all Services.

(2) Department of Defense and Federal facilities available for USAR execution of the SVP. Immunizations should be available at times and places other than at TPU locations during drill weekends or during Annual Training. The United States Army Medical Command (MEDCOM) will assist the USAR in determining the optimal location and method for completing smallpox vaccination. Every effort will be made to ensure that smallpox vaccine is available in the selected DoD, other Federal, or contract facilities to ensure that soldiers can obtain immunizations on the day that is required for their individual immunization schedule. The plan will include processes to evaluate smallpox vaccination responses.

e. Contract Funding. Upon request, OCAR Program Analysis and Evaluation (PAE) Division will provide input to MEDCOM Resource Management concerning development of any USAR Statement of Work (SOW) for use by Federal Agencies or civilian contractors.

f. Prioritization of Troop Populations. The USARC, AR-PERSCOM, 7th ARCOM, 9th RSC, and USASOC will prioritize troop populations to receive immunization IAW HQDA prioritization guidance. Priorities will be as follows:

(1) Forces assigned or rotating to higher threat areas as delineated.

(2) Selected Reserve (SELRES) forces.

(3) Remainder of Total Force and accessions.

g. Record keeping. Annotation of immunizations to medical records (MEDPROS, SF 601, and PHS Form 731) per the basic plan will be accomplished by the medical treatment facility or contractor administering the vaccination. The plan will include processes to evaluate smallpox vaccination responses.

h. Tracking System. Immunizations will be entered into the DA-designated automated immunization tracking system (MEDPROS) IAW ANNEX J and reported IAW ANNEX F. Commanders, USARC, AR-PERSCOM, 7th ARCOM, 9th RSC, and USASOC will develop procedures to identify all personnel requiring access to the automated tracking system, ensure they meet access requirements, and determine data access level IAW ANNEX J.

i. Logistics. The U.S. Army Medical Material Agency (USAMMA) will direct the distribution of the vaccine to FEDS_HEAL providers, USAR units and, when applicable, supporting Installation Medical Supply Activities (IMSAs) per ANNEX D. IMSAs will coordinate directly with the designated medical facilities or providers for distribution of the vaccine to the immunization sites. Ancillary supplies will be the responsibility of the immunizing entity per the basic plan.

j. Adverse Events.

(1) Commanders will establish a mechanism to monitor the incidents of adverse events that occur after the soldier has been released from military control. See ANNEX C, Part 8.b., for adverse event reporting requirements.

(2) Army Reserve members or family members who experience adverse events and are seeking health services outside of a Military Treatment Facility must contact the Military Medical Support Office (MMSO) at 1-888-647-6676 for guidance.

(3) Commanders will ensure a line of duty determination is completed for all adverse events, regardless of whether or not medical care is sought or the source of such care.

k. Public Affairs Office (PAO) Information. Commanders at all levels will support an aggressive command information program in support of the SVP. Commanders must use and will not deviate from the PAO information provided by HQDA. This program will include:

(1) Threat briefing.

(2) SVP specific information as outlined in the basic plan and ANNEX E.

l. Resource Management. The Office of the Chief, Army Reserve (OCAR), PAE Division, will provide MEDCOM with the USAR SVP cost estimates for the development of Program Objective Memorandum (POM) submission to the DHP. This funding estimate will provide for immunization services and for future SVP activities, defined in the basic plan as determined by DoD and HQDA.

4. RESPONSIBILITIES.

a. OCAR will provide appropriate USAR immunization prioritization guidance (for identification of USAR units and personnel to be immunized) through command channels to USARC, AR-PERSCOM, 7th ARCOM, 9th RSC, and USASOC.

b. USARC will develop an implementation plan in coordination with MEDCOM.

c. AR-PERSCOM will develop an implementation plan in coordination with MEDCOM.

d. 7th ARCOM will develop an implementation plan in coordination with European Regional Medical Command and MEDCOM.

e. 9th RSC will develop an implementation plan in coordination with Pacific Regional Medical Command, Western Regional Medical Command, 18th Medical Command, and MEDCOM.

f. USASOC will develop an implementation plan for assigned USAR soldiers in coordination with MEDCOM.

ANNEX I - DEPARTMENT OF THE ARMY CIVILIANS AND DOD CONTRACTORS

1. GENERAL.

a. Smallpox vaccination will be mandatory for DA civilians in designated "Emergency Essential" (E-E) positons and civilian contractor personnel carrying out "mission essential" (ME) services, who are eligible for vaccination IAW paragraph 3.a., this basic plan. For civilian personnel in category 1.f.(5), vaccination shall not be mandatory; these personnel should be offered and encouraged to receive FDA-licensed smallpox vaccine, unless medically exempted. For vaccinations of civilian personnel, ensure all bargaining obligations are fulfilled IAW Federal Services Labor Management Relations Statute prior to implementation.

b. Commanders may also identify and recommend other cohorts of personnel for vaccination against smallpox though the Executive Agent to the ASD(HA), if they deem their occupations may place them at higher risk for exposure to smallpox. Send requests to HQDA, Office of The Surgeon General, Military Vaccine Agency, 5109 Leesburg Pike, Falls Church, VA 22041 for coordination with and approval by HQDA, CJCS and ASD(HA).

c. DoD Directive 6205.3, DoD Immunization Program for Biological Warfare Defense, dated 26 Nov 93, applies to essential DoD civilian personnel, and personnel of other Federal Departments, when assigned as part of the U.S. Armed Forces. DoD Directive 1404.10, "Emergency-Essential (EE) DoD U.S. Civilian Employees," addresses policy to ensure the continued performance of civilians that have been designated EE before crisis situations; it also addresses civilians who have not been previously designated EE, but whose continued performance is deemed essential to support combat-essential systems. DoD Instruction 3020.37, "Continuation of Essential DoD Contractor Services During Crises," dated 6 Nov 90, with Change 1 dated 26 Jan 96, states that employees designated as mission essential must be identified as such in the contract statement of work (SOW). DoD civilians and contractors are subject to the same vaccination requirements as active-duty personnel upon deployment. For contract personnel the designation as "Emergency Essential" would appear in the contract.

d. Command-directed smallpox vaccinations are administered without charge to civilian employees.

e. EE civilians and ME contractors will be vaccinated IAW with MACOM guidelines, in most cases going to the nearest MTF for vaccination.

2. CONSENT FOR IMMUNIZATION.

a. Civilian employee immunization is given with consent. All employees will be encouraged to accept smallpox vaccination when offered. However, in instances where smallpox vaccination for civilians is mandatory, vaccination will be a condition of employment.

b. The effect on a Department of the Army employee who refuses immunization when indicated will be determined by the appropriate supervisor or commander in conjunction with representatives of the Civilian Personnel Office and the servicing legal office. Army policy requires that management first consider taking a non-adverse action, such as a reassignment to a non-EE position; identification of an alternate employee who is willing to be immunized and serve as an EE; curtailment of tour, etc. If none of these are possible, the EE could be subject to adverse actions, up to and including, removal from the federal service for failure to meet a condition of employment. Refusal of smallpox immunization should be documented in appropriate personnel and health records.

3. DOCUMENTATION.

a. Education. Supervisors will be responsible for ensuring that civilian employees are adequately trained and aware of the health risk of smallpox as a biological weapon, and document that this training was received. Supervisors are responsible for ensuring compliance with the education requirements for vaccine recipients detailed in Annex E, paragraph 6.a.(1).

b. Refusal of immunization must be documented as indicated in Part 2. b. in this ANNEX.

c. Documentation of immunization.

(1) All smallpox immunizations will be recorded in the appropriate health record and on a PHS Form 731. Written entries will contain the data elements described in ANNEX C. Civilian smallpox immunizations will also be recorded in the Army's automated immunization tracking system, MEDPROS, IAW ANNEX J.

(2) Serious adverse events to immunization will be recorded in the occupational health record, and reported through the Army Medical Surveillance System IAW ANNEX C.

ANNEX J - IMMUNIZATION TRACKING SYSTEM

1. PURPOSE. To provide the concept of operations for tracking smallpox vaccinations using an automated Immunization Tracking System (ITS).

2. GENERAL INFORMATION.

a. The Army will vaccinate forces against smallpox IAW the FDA immunization protocol and DoD policy. The smallpox vaccine is administered in one dose according to FDA protocol.

b. Soldiers and civilians who receive smallpox vaccine may change duty stations, be deployed and/or be on leave. An automated ITS provides visibility to these personnel and their commanders or supervisors of the individual's immunization status, and ensures that their immunization history will be annotated in their permanent electronic data record.

3. CONCEPT OF OPERATIONS.

a. The Army uses the Medical Protection System (MEDPROS) as its automated ITS to track smallpox vaccinations. MEDPROS is a subset of the Medical Operational Data System (MODS). The MODS system resides on a mainframe computer system at the Pentagon. MEDPROS is a modem, easy to use, web-based tracking system, accessed from the Internet at http://www.mods.army.mil/.

(1) Users may request a LOGON ID directly from the website or may call the MODS help desk at the numbers in paragraph 6, this ANNEX, for assistance. The MODS help-desk is manned 24 hours a day to assist you with MEDPROS-related questions.

(2) Required ITS data elements include: patient name, SSN, date of immunization, name of vaccine, lot number, manufacturer, and route of administration, name of provider, documented take recorded, and consent form (if required).

(3) All smallpox immunizations will be recorded in MEDPROS within 24 hours of the immunization event.

(4) Immunizations will be posted in the patient's paper health record IAW ANNEX C.

(5) Vaccination response will be entered in the "REACT" or "REACTION" field after the vaccination site is evaluated 6 to 8 days after vaccination. The immunization record will be annotated with "MAJOR" for major reaction or "EQUIV" for an equivocal reaction, using the definitions adopted by the World Health Organization and the Centers for Disease Control and Prevention.

b. MEDPROS Training. Classroom training is available at the MODS contractor main location in CONUS in northern Virginia. Additionally, civilian MODS contractors will be available on a limited basis for off-site training. The MODS contractor and the OTSG/MEDCOM Military Vaccine Agency (MILVAX) also have regional analysts who are available on a limited basis to provide "train the trainer" courses across MEDCOM and the Army. To arrange MEDPROS training, contact the MODS help desk or call the MILVAX senior program analyst at the numbers in paragraph 6, this ANNEX.

(1) Classes are 12-16 hours long (depending on level of training) and include orientation, demonstration, and practical exercises. For off-site training, a classroom with computer terminals is required with no more than two students per terminal. Terminals must be able to access a Local Area Network (LAN), a Wide Area Network (WAN), or have modems for Terminal Server Access Connection System (TSACS)/internet access. MEDCOM developed the Enhanced Remote Immunization Data Entry System (RIDES-E) for units that do not have LAN, WAN or Internet access. RIDES-E requires the use of a lap top computer with a CD reader. You can contact the MODS help desk for information on implementing this system.

(2) Those personnel who actually enter immunization data (into MEDPROS) at point of service of immunizations should be targeted for training; i.e. personnel at immunization clinics, Troop Medical Clinics and all levels of Command through battalion level who are responsible to the Commander to enforce vaccination schedules and keep the Commander informed (Battalion/ Brigade S1s, PSNCOs, etc). Ideally, personnel/units who are scheduled for deployment to designated areas should get MEDPROS training BEFORE they deploy, as training in CONUS is not as problematic.

c. Other Services' military members, Department of Defense Civilian Employees and DoD Contractors may receive their vaccinations at Army MTFs IAW this plan and will be tracked using MEDPROS. Immunizations will be recorded in MEDPROS for non-military Army personnel by adding their names utilizing the task force function. The MEDPROS system will report smallpox immunization data to DEERS. Other services will gain visibility of their members vaccinated in Army facilities from the DEERS reports. MEDPROS will also read data from DEERS and record confirmation of soldiers receiving smallpox immunizations from another service (MEDPROS queries DEERS on a monthly basis for this purpose). DEERS is the central repository for the smallpox immunization data and will provide reports as required.

4. RESPONSIBILITIES.

a. U.S. Army Medical Command.

(1) Field MEDPROS and RIDES-E and train users.

(2) Provide oversight for Immunization Tracking System.

(3) Maintain quality control of the immunization tracking process performing checks for accuracy as necessary and ensuring that all smallpox immunizations are recorded within the MEDPROS system within 24 hours of the immunization event.

b. 18th Medical Command.

(1) Provide oversight for Immunization Tracking Program on the Korean Peninsula.

(2) Record all smallpox immunizations within the MEDPROS system within 24 hours of the immunization event.

(3) Maintain quality control of the immunization tracking process performing checks for accuracy as necessary. Report discrepancies to HQ MEDCOM.

5. REPORTING: The following reports will be available from MEDPROS:

a. Individual immunization status report by SSN.

b. List of personnel by UIC that are due for a specific immunization by type and series.

c. Percent of personnel by UIC who are due a specific immunization by type and series.

d. Percent of personnel by UIC who have received the immunization.

e. List of personnel by UIC who have received the immunization.

6. COORDINATING INSTRUCTIONS. USAMEDCOM DCSOPS will serve as the single point of contact for questions and/or problems experienced with MEDPROS. POCs for MEDPROS are:

a. USAMEDCOM DCSOPS: Medical Readiness and Training Branch, Operations Division
Comm: (210) 221-7124
DSN: 471-7124
FAX: 471-7061

b. MODS Help Desk
ASM Research, MODS Project Office:
Comm: (703) 681-4976/5008 or 1-888-849-4341
DSN: 761-4976/5008
International toll-free, Korea: 0-130-81-9261
International toll-free, Germany: 00798-14-8002803

c. Military Vaccine Agency, Senior Program Analyst
MEDPROS training coordinator.
Comm: 1-703-681-1692 or 1-877-GETVACC



DEPARTMENT OF THE ARMY
OFFICE OF THE VICE CHIEF OF STAFF
201 ARMY PENTAGON
WASHINGTON DC 20310-0201

REPLY TO
ATTENTION OF

MEMORANDUM FOR SEE DISTRIBUTION

10 JAN 2003

SUBJECT: Army Smallpox Vaccination Program Implementation Plan

1. The Department of Defense established the Smallpox Vaccination Program (SVP) to protect the health and safety of our personnel and preserve certain mission critical capabilities. The Army SVP Implementation Plan is enclosed. Commanders will prepare supporting plans to execute this program immediately for servicemembers only, beginning as soon as plan requirements are met. I will transmit a separate directive to the MACOMs directing implementation of the SVP for civilian employees after national labor relation's obligations have been met.

2. The SVP is a commander's responsibility to better ensure force health protection. I want to emphasize four important program components:

- **Identify personnel** to be vaccinated. The Army must vaccinate personnel at occupational risk for smallpox exposure and to ensure mission critical capabilities in accordance with DoD policy. Proper pre-vaccination screening will best ensure people at highest risk for serious adverse events are not vaccinated.
- **Educate personnel** prior to vaccination. I hold Army leaders responsible for the education of their personnel. Your education tools are available at www.smallpox.army.mil. Team with local healthcare personnel to help you.
- **Track vaccinations.** Medical personnel will document vaccinations in Health Records and the Army's automated immunization tracking system, MEDPROS. Commanders will ensure tracking is accomplished and monitor their personnel's compliance using the on-line commander's tools MEDPROS provides. HQDA monitors MACOM compliance metrics using MEDPROS.
- **Get personnel medical evaluation** if they experience symptoms following smallpox vaccination; each deserves individual care and follow-up. Report adverse reactions to the FDA.

4. I urge Army leaders—officers, noncommissioned officers, and civilian supervisors—to give the SVP your personal attention to best protect our Army.

Enclosure

John M. Keane
General, United States Army
Vice Chief of Staff

DACS-ZB
SUBJECT: Army Smallpox Vaccine Program Implementation Plan

DISTRIBUTION:
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MILITARY TRAFFIC MANAGEMENT COMMAND
DIRECTOR, ARMY NATIONAL GUARD
CHIEF, ARMY RESERVE

ARMY SMALLPOX PREPAREDNESS AND VACCINATION PROGRAM IMPLEMENTATION PLAN

REFERENCES: See ANNEX A

1. SITUATION.

a. The Deputy Secretary of Defense approved the Department of Defense (DoD) Smallpox Response Plan and directed execution of the Smallpox Vaccination Program (SVP), in accordance with Food and Drug Administration (FDA) guidelines and consistent with the best practice of medicine, to protect selected personnel at highest risk and preserve certain mission critical capabilities. This program supports the national smallpox preparedness plans, but is tailored to the unique requirements of the Armed Forces.

b. The SVP is a command responsibility as part of force health protection. Commanders are responsible for program implementation, to include education of their personnel, tracking of smallpox vaccinations and compliance with FDA requirements.

c. The Secretary of the Army (SECARMY) is the Executive Agent for the SVP, responsible for: vaccine acquisition and stockpiling; to manage and direct the vaccination of identified personnel within the Uniformed Services consistent with DoD policy, the threat, availability of FDA-approved smallpox vaccine, and priorities established by the Chairman of the Joint Chiefs of Staff; to issue operational instructions to the Services; to serve as a focal point for submission of information from the Services; to monitor Services' implementation; to recommend appropriate SVP changes to the Assistant Secretary of Defense (Health Affairs); to execute the Army's implementation plan; and to report quarterly on program execution.

d. The Office of The Surgeon General, through its Military Vaccine Office (MILVAX) will perform the day-to-day functions assigned to SECARMY for all Executive Agent functions, except vaccine acquisition and stockpiling, and keep the SECARMY informed through the Army's SVP Senior Military Official, The Vice Chief of Staff.

e. The Program Executive Office for Chemical and Biological Defense (PEOCBD)—formerly the Joint Program Office for Biological Defense (JPO-BD)—will perform the function of vaccine acquisition and stockpiling assigned to SECARMY, assuring an adequate supply of smallpox vaccination products, and defining production capabilities on behalf of all Services. PEOCBD will keep the MILVAX informed of all vaccine acquisition, stockpiling, and production issues.

f. The Army will vaccinate the following personnel eligible for smallpox vaccinations per Paragraph 3.a., this plan:

(1) Military personnel;

(2) DA civilian personnel classified as emergency-essential under DoD Directive 1404.10, "Emergency-Essential (E-E) DoD U.S. Citizen Civilian Employees, " 10 Apr 99;

(3) Contractor personnel performing mission essential services as described in DoD Instruction 3020.37, "Continuation of Essential DoD Contractor Services During Crisis," 6 Nov 90, with Change 1 dated 26 Jan 96;

(4) Other personnel categorized as alert forces, as defined in the joint regulation on Immunizations and Chemoprophylaxis (AR 40-562);

(5) Other civilian employees who are designated members of a smallpox response team (e.g., smallpox epidemiological team, treatment team, public health team).

Vaccination is mandatory for personnel in categories 1.f.(1), (2), (3), and (4), except as provided under applicable administrative (ANNEX B) and medical (ANNEX C) exemption policies. For civilian personnel

in category 1.f.(5), vaccination shall not be mandatory; these personnel should be offered and encouraged to receive FDA-licensed smallpox vaccine, unless medically exempted. For vaccinations of civilian personnel, ensure all bargaining obligations are fulfilled IAW Federal Services Labor Management Relations Statute prior to implementation.

(6) In those instances where individuals are not able to take smallpox vaccine due to: (1) an administrative exemption, granted by a commander or supervisor, discussed in detail in ANNEX B; or (2) a medical exemption granted by a privileged healthcare provider (e.g. physicians, nurse practitioners, and physician assistants), discussed in detail in ANNEX C, he/she is still deployable.

2. MISSION. Headquarters Department of the Army (HQDA) implements the DoD Smallpox Response Plan and Smallpox Vaccination Program to preserve certain mission critical capabilities against smallpox (variola virus) and protect selected personnel at highest risk.

3. CONCEPT OF OPERATIONS.

a. **Identify and Vaccinate Eligible Personnel IAW DoD Policy.** The Army will vaccinate personnel in accordance with (IAW) the Office of the Secretary of Defense (OSD) and Joint Chiefs of Staff (JCS) guidance (ANNEX A). The Army will vaccinate designated personnel in stages:

(1) Stage 1a. Smallpox Response Teams. DoD's Smallpox Response Plan requires these response teams, including designated special mission units, medical epidemiological response teams, and the Army National Guard Civil Support Teams (CST).

(2) Stage 1b. Selected Healthcare Workers. The Army will vaccinate selected healthcare workers at most installations, especially those with inpatient capabilities. This will give the Army the capability to respond to a smallpox attack IAW the DoD Smallpox Response Plan.

(3) Stage 2. Designated forces that constitute certain mission-critical capabilities. These include certain forces deployed or assigned overseas, forces that would be expected to deploy in a contingency, and forces that enable such contingency forces to deploy. At this time, the Secretary of Defense has limited implementation of this stage to that part pertaining to U.S. Central Command's missions. Army will publish supplemental classified guidance for Stage 2 implementation.

(4) Near-term SVP implementation may also include other personnel determined by the Assistant Secretary of Defense for Health Affairs (ASD(HA)), in consultation with the Chairman of the Joint Chiefs of Staff (CJCS), to be at higher risk of exposure to Smallpox. Commanders may submit requests for exceptions for others not covered by DoD policy to be vaccinated against smallpox through MACOMs to HQDA, Office of The Surgeon General, Military Vaccine Agency, 5109 Leesburg Pike, Falls Church, VA 22041 for coordination and approval with ASD(HA) and CJCS.

b. **Mandatory Vaccination Policy.** The smallpox vaccine is mandatory for designated personnel in paragraphs 1.f.(1), (2), (3), and (4) this plan, unless specifically exempted through: (1) an administrative exemption, granted by a commander or supervisor, discussed in detail in ANNEX B; or (2) a medical exemption granted by a privileged healthcare provider (e.g. physicians, nurse practitioners, and physician assistants), discussed in detail in ANNEX C, using the standard form at http://www.smallpox.army.mil/media/pdf/Vacciniainitial.pdf. For civilian personnel in category 1.f.(5), vaccination shall not be mandatory; these personnel should be offered and encouraged to receive FDA-licensed smallpox vaccine, unless medically exempted. For vaccinations of civilian personnel, ensure all bargaining obligations are fulfilled IAW Federal Services Labor Management Relations Statute prior to implementation. As with all immunizations, military personnel do not have the option to refuse immunization. IAW AR 600-20, Army Command Policy, commanders can order their soldiers to be immunized. Although each case will be determined on its own merits, soldiers refusing an order may face adverse administrative action or disciplinary action under the Uniform Code of Military Justice. Coordinate disciplinary actions subsequent to any vaccination refusal with your servicing judge advocate or legal advisor. ANNEX B discusses vaccination refusal management further.

c. **Vaccine Requisition and Distribution.** The U.S. Army Medical Materiel Agency (USAMMA) will coordinate the distribution of the vaccine and ancillary products to the supporting medical supply activities of all Services per ANNEX D. End-users will directly requisition vaccine IAW USAMMA guidelines in ANNEX D as required for SVP sustainment.

d. **Education of Personnel to be Vaccinated.** Commanders and Army leaders at all levels are responsible to educate their personnel before vaccination and identify people exempt from smallpox vaccination. At a minimum, Commanders and other leaders will brief their eligible personnel and provide them a copy of the informational trifold as outlined in ANNEX E. Your local medical treatment facility will maintain a stock of trifolds for your use. Team with local healthcare providers and other subject matter experts (e.g., staff judge advocate, public affairs offices) to assist with this education, screening for exemptions, and answering questions upfront. Current education tools are always available at www.smallpox.army.mil. ANNEX E also details the Army's public affairs strategy.

e. **Options For Personnel with Medically Exempt Household Contacts.** Commanders will actively manage their personnel who are temporarily medically exempt from smallpox vaccination due to a household contact who has a medical contraindication and ensure their vaccination when that household contact exemption no longer applies. Commanders basically have two options, either (1) arrange for alternate housing from day of vaccination until the vaccination scab falls off (about 14 to 21 days), or (2) vaccinate the person when the exemption no longer applies (e.g., after family separation during mobilization or at time of deployment). See Appendix 1 to ANNEX C for examples of acceptable and unacceptable situations.

f. **Adverse Event Management.** Provide people with appropriate medical evaluation if they experience symptoms following smallpox vaccination. Some symptoms and complaints may be caused by the vaccine—others may not—but each deserve appropriate medical attention, individual concern, and empathy. If symptoms persist, providers, leaders, or patients may contact the Walter Reed Vaccine Healthcare Center at 202.782.0411, for appropriate consultation, advice, and specialized medical management. Report adverse reactions IAW ANNEX C, AR 40-562, and AR 40-3. MILVAX will track reports of adverse events and report to The Surgeon General routinely.

g. **Immunization Tracking and Compliance.** Commanders and healthcare personnel have dual roles ensuring smallpox vaccinations are documented in healthcare records and the Army's automated immunization tracking system, the Medical Protection System (MEDPROS) IAW ANNEXES C and J. The HQDA standard for SVP execution is 90% compliance of eligible personnel receiving their smallpox vaccinations or having exemptions noted in MEDPROS. HQDA will monitor Army MACOMs' performance using these metrics through MEDPROS. MEDPROS not only tracks the immunization record, but offers commanders a powerful tool to manage SVP immunization within their units from their desktop computer.

h. **Coordinating Vaccination.** To deliver this immunization, the Army will use military medical assets (including those organic to the units); Veterans Administration Sharing Agreement, an MOA with the Public Health Service's Federal Occupation Health Division, and a private sector contract to deliver this immunization. The U.S. Army Medical Command (USAMEDCOM), Army National Guard (ARNG) (ANNEX G), and U.S. Army Reserve (USAR) (ANNEX H) will assist these medical providers to execute this plan.

4. RESPONSIBILITIES.

a. Army MACOMs.

(1) Develop supporting plans to execute smallpox immunizations IAW this plan.

(2) Incorporate smallpox vaccination information IAW ANNEX E into Command Information Programs.

(3) Implement procedures to ensure that in-processing and out-processing at subordinate installations include a screen to ascertain smallpox vaccination status and ensure compliance with this plan.

(4) Direct installations develop local supporting plans to the DoD Smallpox Response Plan.

b. Office of The Surgeon General/US Army Medical Command.

(1) Provide vaccination support in coordination with Army MACOMs in support of their vaccination plans.

(2) Provide vaccination support to the Army National Guard and U.S. Army Reserves IAW ANNEXES H and I, respectively.

(3) Provide vaccination support to other Services IAW OASD(HA) guidance.

(4) Provide vaccine and ancillary supplies IAW ANNEX D, to units conducting vaccinations.

(5) Develop and disseminate medical information, policy, and doctrine as required.

(6) Receive and consolidate reports of adverse events from all Services. Provide summary reports to The Surgeon General.

(7) Issue specific guidance and direct identification of Stage 1b healthcare workers within MEDCOM.

(8) Establish smallpox vaccination training standards and facilitate training and training documentation.

(9) As part of MEDCOM's Organization Assessment Program (OAP), perform audits of immunization records for quality-assurance purposes, to assure completeness of data entry and agreement of paper and electronic immunization records.

c. The Program Executive Office for Chemical and Biological Defense (PEOCBD).

(1) Execute procedures to procure and store the smallpox vaccine IAW OSD guidelines.

(2) Program future resources necessary to support the Department's Medical Biological Defense Program against smallpox.

5. COORDINATING INSTRUCTIONS.

a. Direct coordination with Navy, Marine Corps, Air Force, and Coast Guard medical facilities is authorized.

b. Funding for vaccine will be provided by the PEOCBD. Ancillary supplies will be funded from the Defense Health Program (DHP).

c. For military personnel, MACOMs have the authority to execute this plan and vaccinate immediately upon meeting the requirements for: appropriate identification of personnel to be vaccinated IAW DoD policy and ANNEX C; vaccine distribution and storage; prevaccination education; documentation and tracking vaccinations and compliance with the program; and ability to evaluate and report suspected adverse reactions, outlined in this plan.

d. Before beginning smallpox vaccinations at any installation, preventive medicine staff will contact their counterparts at city, county, and state public health departments to inform them that smallpox vaccinations will begin in the near future.

e. Proponent of this plan is the Office of The Surgeon General, Directorate of Healthcare Operations, Military Vaccine Agency, DASG-HCA, DSN 761-5101, COMM (703) 681-5101.

6. ANNEXES.

a. ANNEX A, REFERENCES
b. ANNEX B, ADMINISTRATIVE CONSIDERATIONS AND GUIDANCE
c. ANNEX C, MEDICAL CONSIDERATIONS AND GUIDANCE
d. ANNEX D, LOGISTICS
e. ANNEX E, EDUCATION/COMMUNICATIONS PLAN
f. ANNEX F, PERSONNEL
g. ANNEX G, ARMY NATIONAL GUARD
h. ANNEX H, U.S. ARMY RESERVE
i. ANNEX I, DEPARTMENT OF THE ARMY CIVILIANS AND DOD CONTRACTORS
j. ANNEX J, IMMUNIZATION TRACKING

ANNEX A - REFERENCES

1. Department of Defense Directive (DoDD) 6205.3, DoD Immunization Program for Biological Warfare Defense, 26 November 1993. http://www.dtic.mil/whs/directives/corres/pdf/d62053_112693/d62053p.pdf

2. AR 40-2, Army Medical Treatment Facilities General Administration, 15 March 1983. http://www.usapa.army.mil/pdffiles/r40_2.pdf

3. AR 40-68, Quality Assurance Administration, 20 December 1989. http://www.usapa.army.mil/pdffiles/r40_68.pdf

4. Memorandum of Understanding Between the U.S. Army Medical Command and U.S. Army Reserve Command, 11 May 1995.

5. CDC Smallpox Response Plan, Guide B, Vaccination Guidelines for State & Local Health Agencies, 23 September 2002. http://www.bt.cdc.gov/DocumentsApp/Smallpox/RPG/.

6. CDC Smallpox Response Plan, Annex 2, Guidelines for Smallpox Vaccination Clinics, 23 September 2002. http://www.bt.cdc.gov/DocumentsApp/Smallpox/RPG/.

7. CDC Smallpox Response Plan, Annex 3, Vaccine Adverse Events Reporting, 23 September 2002. http://www.bt.cdc.gov/DocumentsApp/Smallpox/RPG/.

8. US Army Medical Department. Clinical Guidelines for Managing Adverse Events After Vaccination, 22 August 2002. http://www.anthrax.mil/media/pdf/cpguidelines.pdf and http://www.anthrax.mil/media/pdf/algorithm.pdf.

9. National Vaccine Advisory Committee. Adult immunization programs in nontraditional settings: Quality standards and guidance for program evaluation. *MMWR* 2000; 49(RR-1): 1-13. http://ftp.cdc.gov/pub/Publications/mmwr/rr/rr4901.pdf.

10. Advisory Committee on Immunization Practices. Vaccinia (smallpox) vaccine. *MMWR* 2001; 50(RR-10): 1-25. http://www.cdc.gov/mmwr/PDF/rr/rr5010.pdf. Supplemented by Summary of October 2002 ACIP Smallpox Vaccination Recommendations, 21 October 2002, http://www.bt.cdc.gov/agent/smallpox/vaccination/acip-recs-oct2002.asp.

11. DoD Smallpox Response Plan, version 3.1, 29 September 2002, http://www.smallpox.army.mil/media/pdf/DODSpoxPlan.pdf

12. AR 40-3, Medical, Dental, and Veterinary Care, 30 July 1999.

13. DEPSECDEF Memo, Subject: Department of Defense Smallpox Response Plan, 30 September 2002.

14. ASD(HA) Memo, Subject: Clinical Policy for the DoD Smallpox Vaccination Program (SVP), 26 November 2002.

15. USD(P&R) Memo, Subject: Policy on Administrative Issues Related to Smallpox Vaccination Program (SVP), 13 December 2002.

16. DoD Directive 1404.10, "Emergency-Essential (E-E) DoD U.S. Citizen Civilian Employees," 10 April 1999.

17. DoD Instruction 3020.37, :Continuation of Essential DoD Contractor Services During Crisis, " 6 November 1990, with Change 1 dated 26 January 1996.

ANNEX B - ADMINISTRATIVE CONSIDERATIONS AND GUIDANCE

1. Administrative Exemptions.

a. This section provides criteria for administrative exemptions for selected personnel subject to the DoD Smallpox Vaccination Program (SVP). It does not apply to medical exemptions. Army commanders and civilian supervisors at all levels are designated as exemption authority to grant administrative exemptions per this Annex for the DoD SVP.

b. Administrative exemption is applicable to retiring and separating personnel (without Reserve Component (RC) obligations and who do not plan to immediately re-enlist) and civilian employees and contractor personnel leaving a position subject to the SVP with 30 days or less of service or employment remaining. This administrative exemption does not apply to personnel whom the commander determines shall receive the vaccine because of overriding mission requirements.

c. Exemption authorities shall exempt from the SVP those personnel separating within 30 days (as described further below) who meet all of the following conditions: (a) they are not currently assigned or deployed to a designated higher threat area; (b) they are not scheduled to perform duty in a designated higher threat area; and, (c) the exemption authority has not directed vaccination because of overriding mission requirements. Personnel who meet these criteria should immediately identify themselves to their commanders and supervisors.

d. To calculate the 30-day period, the following specifications apply. For retiring or separating military personnel, the applicable period is 30 days prior to their approved date of retirement or separation. RC members must have approved retirement orders to be effective within 30 days, reassignment date to the Individual Ready Reserve (IRR), or expirations of enlistment within 30 days prior to consideration for exemption from the vaccine. Those personnel who are separating from active duty but continuing service with the Selected Reserve are NOT exempt. For EE and contractor personnel subject to the SVP because of performance of essential contractor services, the applicable period is 30 days prior to the effective date of retirement, resignation, separation, or reassignment out of a position subject to the SVP. All other reserve personnel categories (e.g. IRR, Individual Mobilization Augmentee (IMA)), when mobilized, are subject to smallpox vaccination per this plan and DoD guidance.

e. Granting administrative exemptions is a personnel function, usually controlled by an individual's unit. Exemption authorities will use the following exemption codes for electronic tracking of administrative exemptions in all vaccine recipients in MEDPROS, the Army's automated immunization tracking system (See ANNEX J):

Code	Meaning	Explanation or Example	Duration
AD	Administrative, Deceased	Servicemember/civilian is deceased	Indefinite
AL	Administrative, Emergency Leave	Servicemember/civilian is on emergency leave	Max 1 month
AM	Administrative, Missing	Missing in action, prisoner of war	Indefinite
AP	Administrative, PCS	Permanent change of station	Max 3 months
AR	Administrative, Refusal	UCMJ Actions	Until resolution
AS	Administrative, Separation	Discharge, separation, retirement	Indefinite
AT	Administrative, Temporary	AWOL, legal action pending	Max 3 months

2. Smallpox Vaccine Refusal Management for Servicemembers. Commanders will manage refusal to take the smallpox vaccine (or any vaccine), as they would address any refusal to obey a lawful order and IAW AR 600-20, Army Command Policy. Always coordinate vaccine refusal management with your servicing judge advocate or legal advisor. See Annex I for guidance on civilian employee refusal to take the smallpox vaccine.

a. Per AR 600-20, paragraph 5-4, "A soldier on active duty or active duty for training will usually be required to submit to medical care considered necessary to preserve his or her life, alleviate undue suffering, or protect or maintain the health of others. Commanders may order the examination of any soldier in their command when warranted. The medical treatment facility commander will determine if hospitalization of the soldier is appropriate." In accordance with AR 600-20, Army Command Policy, commanders can order their soldiers be immunized. Although each case will be determined on its own merits, soldiers refusing an order may face adverse administrative action and/or disciplinary action under the provisions of The Uniform Code of Military Justice, Article 92, Failure to obey order or regulation.

b. Immunizations. Commanders will ensure that soldiers are continually educated concerning the intent and rationale behind both routine and theater-specific or threat-specific military immunization standards. Immunizations required by AR 40-562 or other legal directive may be given involuntarily (except as prescribed in paragraph 5-6 of this regulation). The intent of this authorization is to protect the health and overall effectiveness of the command, as well as the health of the individual soldier.

c. Per AR 600-20, "Under normal circumstances, actions will not be taken to involuntarily immunize soldiers." [i.e., hold them down or otherwise restrain them]

d. Commanders will:

(1) Ensure soldiers understand the purpose of the vaccine.

(2) Ensure soldiers are advised of both the endemic, natural threat and potential use as a biological weapon agent.

(3) Ensure soldiers are educated about the vaccine and have been afforded the opportunity to discuss concerns with medical authorities.

(4) Counsel the soldier, in writing, on his or her requirement to be immunized and ramifications for failure to follow a lawful order.

(5) Order the soldier to receive the vaccination.

e. Per AR 600-20, para 5-4.c.(2)(c), "When a General Court-Martial Convening Authority (GCMCA) or his delegated representative determines that conditions of imminent threat exist (where the threat of naturally occurring disease or use of biological weapons is reasonably possible) soldiers may be involuntarily immunized. Involuntary immunization(s) will not be ordered by a commander below the GCMCA unless authority to do so has been properly delegated by the GCMCA. Prior to ordering involuntary immunizations, all of the steps outlined above should be followed, situation permitting. In performing this duty, unit personnel will only use the amount of force necessary to assist medical personnel in administering the immunization."

ANNEX C - MEDICAL CONSIDERATIONS AND GUIDANCE

1. REFERENCES.

a. Air Force Joint Instruction 48-110, Army Regulation 40-562, BUMEDINST 6230.15, and CG COMDTINST M6230.4E, Immunizations and Chemoprophylaxis, November 1, 1995. http://www.e-publishing.af.mil/pubfiles/af/48/afji48-110/afji48-110.pdf

b. Centers for Disease Control and Prevention, Advisory Committee on Immunization Practices. General Recommendations on Immunization. MMWR 2002; 51(RR-2): 1-35. ftp://ftp.cdc.gov/pub/Publications/mmwr/rr/rr5102.pdf.

c. Assistant Secretary of Defense for Health Affairs Memorandum, Clinical Policy for the DoD Smallpox Vaccination Program (SVP), November 26, 2002.

d. US Army Medical Department. Clinical Guidelines for Managing Adverse Events After Vaccination, 22 August 2002. http://www.anthrax.mil/media/pdf/cpguidelines.pdf and http://www.anthrax.mil/media/pdf/algorithm.pdf.

e. Vaccine Healthcare Center website, http://www.vhcinfo.org/.

f. Vaccine Adverse Event Reporting System online reporting, www.vaers.org or https://secure.vaers.org/VaersDataEntryintro.htm.

g. Smallpox Vaccine (Dryvax) Insert. http://www.fda.gov/cber/label/smalwye102502LB.pdf.

h. DoD Smallpox Vaccination Program Website: www.smallpox.army.mil.

i. Memorandum, Commander, US Army Medical Command, Preparing to Defend Against Smallpox. December 23, 2002. http://www.smallpox.army.mil/media/pdf/prepDefmemo1.pdf.

j. Advisory Committee on Immunization Practices. Vaccinia (smallpox) vaccine. *MMWR* 2001; 50(RR-10): 1-25. http://www.cdc.gov/mmwr/PDF/rr/rr5010.pdf. Supplemented by Summary of October 2002 ACIP Smallpox Vaccination Recommendations, 21 October 2002, www.bt.cdc.gov/agent/smallpox/vaccination/acip-recs-oct2002.asp.

k. Army Regulation 600-110, Identification, Surveillance, and Administration of Personnel Infected with Human Immunodeficiency Virus (HIV), 1 June 1996.

2. GENERAL INFORMATION.

a. Vaccine Description.

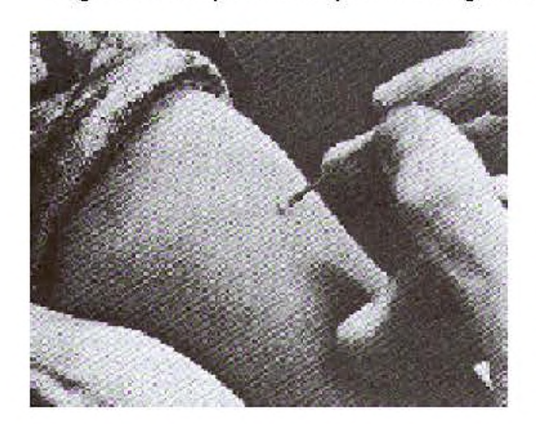
(1) Smallpox Vaccine, Dryvax®, protects more than 95% of healthy people who receive it. Smallpox vaccine contains live vaccinia viruses made from calf lymph, which cross-protect against variola virus, the virus that causes smallpox. Smallpox vaccine will be administered in the standard full-strength concentration (as per original labeled reconstitution instructions), unless the CDC, FDA, or other responsible health authority issues explicit instructions to the contrary.

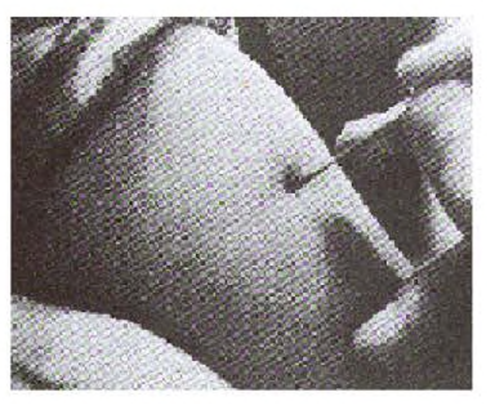
(2) The smallpox vaccine, dried, is manufactured from purified, concentrated lyophilized calf lymph. Polymyxin B sulfate, dihydrostreptomycin sulfate, chlortetracycline hydrochloride, and neomycin sulfate are added during processing and trace amounts may be in the final product. The diluent for Dryvax® contains 50% glycerin, and 0.25% phenol in Sterile Water for injection, USP. Once reconstituted, the vaccine contains approximately 100 million infectious vaccinia viruses per mL, 100 doses per vial. Plan carefully to minimize vaccine wastage that may result from discarding partially used vials.

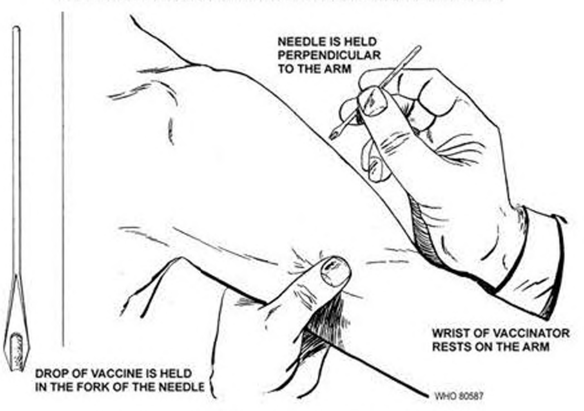
(3) Store reconstituted Dryvax® in the refrigerator between 2° to 8°C (36°to 46°F) Reconstituted Dryvax® may be used for 60 days, according to Dec 02 information from the manufacturer and the FDA, posted on the www.smallpox.army.mil website. This interval may increase to 90 days, if later authorized by the manufacturer and FDA.

(4) Indications and usage. The Advisory Committee for Immunization Practices (ACIP) recommends vaccination to prevent infection with variola virus, the causative agent of smallpox infection. Commanders must take care to identify people who should be exempted from smallpox vaccination due to underlying health conditions.

Figure 1. Proper technique for using bifurcated needle to immunize with smallpox vaccine.







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b. Dosage, Administration, and Response Issues.

(1) Dosage.

Smallpox vaccine is administered in one dose. Inoculate the recipients with a bifurcated needle holding a drop of vaccine and press 3 times for primary vaccination, or 15 times for revaccinations into the skin of the upper arm. Evidence of a prior primary smallpox vaccination includes documentation, or a characteristic Jennerian scar. Presumptive evidence includes entry into U.S. military service before 1984, or birth in the United States before 1970. In general, people should be revaccinated 5 years after

their primary smallpox vaccination and 10 years after subsequent smallpox revaccinations. Specific laboratory workers involved with orthopox virus research may require more frequent vaccination.

(2) Administration Issues.

(a) Vaccination procedures will be consistent with information provided in refs a. and c. Bifurcated needle method is indicated for this vaccine. Preferred injection site is the skin over the deltoid muscle or the posterior aspect of the arm over the triceps muscle. Do not vaccinate near the site of an active lesion. Avoid tattooed skin and skin folds. See Figure 1.

(b) Multiple Vaccinations.

1 Dryvax® may be administered concurrently with other inactivated vaccines, if necessary, or at any interval before or after inactivated vaccines, consistent with ACIP recommendations. See the following paragraph for operational examples. Except for varicella vaccine, smallpox vaccine may be administered simultaneously with other live virus vaccines. To avoid confusion in ascertaining which vaccine may have caused post-vaccination skin lesions or other adverse events, and to facilitate managing such events, varicella vaccine and smallpox vaccine should only be administered 4 weeks apart or greater. If not given simultaneously, live virus vaccines should be separated by 4 weeks or more. Do not administer other vaccines near an active smallpox vaccination site.

2 Ideally, give smallpox vaccine 2 weeks before inactivated vaccines, such as anthrax vaccinations, so those with post-smallpox vaccination malaise between days 8-12 recover before subsequent vaccination. If deployment obligations do not allow this much time, give anthrax vaccination #1 on "day 0." Systemic symptoms, if they occur, would be resolved within 72 hours. Smallpox vaccinations may then be scheduled for "day 3" or "day 4" or later. Distribute any other needed vaccinations (e.g., tetanus-diphtheria, typhoid) on "day 0" or with subsequent anthrax vaccinations.

(c) Needles should be discarded in labeled, puncture-proof containers to prevent inadvertent needle stick injury or reuse.

(d) Because of the nature of the vaccine container, and method of administration, vaccinators' hands should be washed with soap and water or cleansed with an alcohol-based waterless antiseptic solution before and after each patient contact.

(e) Cleansing of the vaccination site may be performed with soap and water, followed by water only, and then drying. Acetone or alcohol may be used only if adequate time is allowed for it to evaporate or if the site is wiped dry with (non-sterile) gauze, to prevent unintentional inactivation of the live virus vaccine.

(f) Practical Tips.

1 During pre-vaccination screening, using the DoD standard screening form (medical note at http://www.smallpox.army.mil/media/pdf/Vacciniainitial.pdf), remind immunization personnel to overcome their tradition of requiring documentation of prior vaccination. Accept oral history of prior smallpox vaccination. Supplement with records, look for an earlier vaccination scar, accept birth before 1971 (i.e., 1 year of age in 1972), or accept military entry before 1984 as presumptive evidence of prior vaccination.

2 Have one or more physicians, physician assistants, or nurse practitioners on site to resolve uncertainties over eczema and atopic dermatitis (or making appropriate clinical referrals), especially in the early norming phases of the SVP.

3 Allow ample time to resolve people's questions. If possible, separate the education-and-screening day from vaccination day.

4 On vaccination day, at the vaccination station, use a team of two vaccinators who trade off duties. One administers the vaccination jabs, while the other acts as blotter, bandager, and documenter. Documentation should include whether the vaccinator sees trace blood, petechia(e), or frank bleeding, as an aid to assure the vaccinator uses sufficient pressure. Have an additional staff member assure completeness of all forms.

5 Locate the vial of smallpox vaccine toward the back of the vaccination station, so that items are not passed over an open vial. A hole may be carved in a Styrofoam block to prevent the small vial from being accidentally bumped and spilled. During prolonged vaccination sessions, place the vial on a cooling (but not freezing) block, tray, or plate.

6 Flight surgeons should record background rates of "duties not including flying" (DNIF) among aviators before initiating smallpox vaccinations, to determine effects of smallpox vaccination on DNIF rates.

7 Use the standard DoD follow-up note for checking vaccination takes and assessing adverse events (http://www.smallpox.army.mil/media/pdf/VacciniaFollowup.pdf).

8 Thirty-day diary cards are available for clinical or personal use (http://www.smallpox.army.mil/media/pdf/diarycard.pdf).

(3) Care of the Vaccination Site.

(a) Vaccinia virus can be cultured from the site of primary (first) vaccination beginning at the time of development of a papule (i.e., 2 to 5 days after vaccination) until the scab separates from the skin lesion (i.e., 14-21 days after vaccination). During that time, care must be taken to prevent spread of the virus to another area of the body or to another person by inadvertent contact. Disease transmission from intact scabs is unlikely, but high-risk individuals may be vulnerable to scab particles.

(b) The most critical measure in preventing inadvertent contact spread is thorough hand washing after changing the bandage or any other contact with the vaccination site, using an alcohol-based waterless antiseptic solution, or soap and water.

(c) To avoid secondary infection, commanders and noncommissioned officers will direct physical activities so that smallpox vaccination sites are not subject to undue pressure (pressure reasonably likely to burst a pustule), rubbing, or immersion sufficiently prolonged to cause maceration or secondary infection. Activities that complicate vaccine site care and cleanliness should be avoided during the post-vaccination healing period. Avoid contact sports, such as wrestling. Avoid immersion in public pools or spas.

(d) If bandages are used to cover the site in a medical setting, dispose of contaminated bandages and the vaccination scab as biohazardous waste. In other settings, dispose of these items in sealed plastic bags (e.g., Ziploc® bag). Clothing, towels, sheets, or other cloth materials that have had contact with the site can be decontaminated with routine laundering in hot water with detergent or bleach. Normal bathing can continue, but the vaccination site should otherwise be kept dry. Avoid rubbing the vaccination site.

(e) Recently vaccinated healthcare workers should minimize contact with unvaccinated patients, particularly those with immune deficiencies, until the scab falls off. Even patients vaccinated in the past may be at increased risk due to current immunodeficiency. If contact with unvaccinated patients is essential and unavoidable, healthcare workers can continue to have contact with patients, including those with immune deficiencies, as long as the vaccination site is well-covered and thorough hand-hygiene is maintained. In this setting, a more occlusive dressing might be appropriate. Semi-permeable polyurethane dressings (e.g., Opsite®, Tegaderm®, Cosmopore®) are effective barriers to vaccinia and recombinant vaccinia viruses. To prevent accumulation of exudates, cover the vaccination site with dry gauze, and then apply the dressing over the gauze. The dressing should also be changed daily or every

few days (according to type of bandaging and amount of exudates), such as at the start or end of a duty shift. Military treatment facilities should develop plans for site-care stations, to monitor workers' vaccination sites, promote effective bandaging, and encourage scrupulous hand hygiene. Wearing long-sleeve clothing can further reduce the risk for contact transfer.

(4) Vaccination-Response Assessment. Assessment of vaccine "take" is required for healthcare workers and for members of smallpox response teams who will travel into a smallpox outbreak area. Other persons receiving vaccine should also have vaccine "take" assessed. To assess vaccine take, medical personnel trained in vaccination evaluation will inspect the vaccination site at 6 to 8 days after vaccine administration. Reactions will be categorized as "Major Reaction" or "Equivocal" in accordance with the World Health Organization (WHO) and FDA-approved product information (package insert). Definitions are below paragraphs 2.b.(4)(a) and (b). To accommodate individuals for whom "take" assessment is not feasible or is otherwise missed, all persons receiving smallpox vaccine will be educated on the expected smallpox vaccination reaction and instructed to report back to a vaccination clinic if they do not develop a characteristic response.

(a) Major Reaction. Indicates that virus replication has taken place and vaccination was successful. Major (i.e., primary) reaction is defined as a vesicular or pustular lesion or an area of definite palpable induration or congestion surrounding a central lesion that might be a crust or an ulcer. The usual progression of the vaccination site after primary vaccination is as follows:

- The inoculation site becomes reddened and pruritic 3-4 days after vaccination.
- A vesicle surrounded by a red areola then forms, which becomes umbilicated and then pustular by days 7--11 after vaccination.
- The pustule begins to dry; the redness subsides; and the lesion becomes crusted between the second and third week. By the end of approximately the third week, the scab falls off, leaving a permanent scar that at first is pink in color but eventually becomes flesh-colored.

Skin reactions after revaccination might be less pronounced with more rapid progression and healing than those after primary vaccinations. Revaccination is considered successful if a pustular lesion is present or an area of definite induration or congestion surrounding a central lesion (i.e., scab or ulcer) is visible upon examination 6--8 days after revaccination.

(b) Equivocal Reaction. Indicates a possible consequence of immunity adequate to suppress viral multiplication or allergic reactions to an inactive vaccine without production of immunity. Equivocal reaction, including accelerated, modified, vaccinoid, immediate, early, or immune reactions, are defined as all responses other than major reactions. If an equivocal reaction is observed, vaccination procedures should be checked and the vaccination repeated by using vaccine from another vial, if available. Difficulty in determining if the reaction was blunted could be caused by immunity, insufficiently potent vaccine, or vaccination technique failure. If the repeat vaccination by using vaccine from another vial fails to elicit a major reaction, healthcare providers should consult a military allergist-immunologist.

(5) Revaccination. If a person does not manifest a characteristic vaccination response 6 to 8 days after smallpox vaccination, that person should receive a single revaccination with 15 punctures (jabs) at a separate site. People previously vaccinated, especially if they have received multiple doses, may not respond to smallpox vaccine because of current immunity. Revaccination should not be repeated more than once in the short term. People previously vaccinated who do not respond with a visible skin lesion after two attempts should be considered medically immune. Others should be referred for immunologic evaluation.

(6) Training. Medical commanders will use standardized materials to train smallpox vaccinators. Healthcare providers must be ready to explain the characteristics of smallpox vaccine to our soldiers, patients, family members, and other beneficiaries. Training resources at www.smallpox.army.mil defines training standards for three categories of healthcare providers who will implement the SVP locally. Within this training tool, participants register and specify their levels of expertise. They will then view a menu of

videotaped presentations. Required training and optional training for each provider level will be displayed. Units may use this web-based tool for their personnel to train on-line, or download the presentations and perform classroom-style training. The three categories of healthcare providers involved in local SVP implementation are:

(a) Medical Director. Serves as the subject-matter expert for the installation commander, working for the MTF Commander. The Medical Director is responsible to the MTF Commander for local execution of the SVP, training of Clinical Consultants and Vaccination Supervisors, and training verification and training documentation of all personnel.

(b) Clinical Consultants and Vaccination Supervisors.

1 Clinical consultants will typically be physicians, physician assistants or nurse practitioners who provide clinical services. Clinical consultants will review screening forms before vaccination and either authorize vaccination, grant exemption from vaccination, or refer vaccine candidates for further evaluation. Clinical consultants may provide classroom education of vaccinees before vaccination.

2 Vaccination supervisors will typically be registered nurses or physician assistants. Vaccination supervisors train and document training of vaccinators and provide direct on-site supervision of vaccinations and vaccination-clinic operations. This may include providing classroom education of vaccinees before vaccination. Vaccination supervisors ensure all vaccinees complete the pre-smallpox vaccination screening form.

(c) Vaccinators. Vaccinators administer vaccinations, provide post-vaccination instructions, and assist vaccinees in obtaining additional information.

(7) Quality Assurance. Medical commanders will assess vaccination technique by evaluating the vaccination take rates among the first cohort of people (e.g., 50 to 100) vaccinated by each vaccinator. Recent published studies found take rates > 95% with appropriate technique.

3. MEDICAL RECORD KEEPING.

a. A permanent entry will be made in the individual's health record IAW AR 40-562 after smallpox vaccine is administered. Entry will include the date of vaccination, name of vaccine, manufacturer, lot number, dose and route of administration, site of administration (e.g. right upper arm) and name of healthcare provider involved in vaccine administration. Current versions of PHS Form 731, International Certificates of Immunization, no longer contain dedicated segments to record smallpox vaccination and responses. In such records, vaccination "take" will be documented in individual health records immediately beneath the vaccination entry by writing the date of the assessment and the type of reaction: either 'Major Reaction' or 'Equivocal.'

b. For deployment, use the DD Form 2766 folder, (Adult Preventative and Chronic Care Flow Sheet) to accompany the individual; copies will remain in the individual's health record.

c. Implement quality-control and quality-assurance measures IAW AR 40-68 to ensure the accuracy of these entries. As part of the routine Organization Assessment Program (OAP), MEDCOM Inspector General will perform audits of immunization records for quality-assurance purposes, to assure completeness of data entry and agreement of paper and electronic immunization records.

4. AUTOMATED IMMUNIZATION TRACKING SYSTEM (ITS).

a. All immunizations will be posted and tracked IAW ANNEX J in the Army's automated Immunization Tracking System, the Medical Protection System (MEDPROS), the HQDA standard for tracking all individual medical readiness indicators in the active and reserve components, as well as DoD civilians and contractors. Leaders at all levels can track individual and unit compliance using MEDPROS from their

desktop. Although various local automated health record systems may be used by clinicians as approved by OTSG/MEDCOM for clinical front-end entry, HQDA requires automated feed into MEDPROS. Local systems not automatically feeding into MEDPROS will not be used.

b. Commanders and healthcare providers are responsible to ensure all smallpox immunizations for their assigned personnel are recorded in MEDPROS within 24 hours of the immunization event.

5. PRE-VACCINATION REQUIREMENTS.

a. Commanders and medical staff will ensure that vaccine recipients are provided adequate information on the vaccine, its safety, its benefits, possible adverse events, contraindications, criteria for medical exemptions for recipients and their household contacts, risks to household contacts and vaccination-site care prior to vaccination. Informational brochures will be distributed to all personnel, military and civilian, before receiving this vaccine.

b. Commanders will provide all vaccine recipients with a briefing on smallpox and the vaccination program. The briefing at Appendix 3, ANNEX E, is provided for this purpose. Updated versions of this briefing will be posted at www.smallpox.army.mil. Vaccine recipients will be provided a color picture of the characteristic smallpox vaccination reaction. Recipients will be instructed that they will have a visual inspection of their vaccination site 6-8 days after receiving vaccine. They will also be instructed that if for some reason they are unable to report for take assessment, they must report back to the vaccination clinic if they do not develop a characteristic reaction.

c. Personnel will be given the opportunity to ask questions of healthcare providers prior to vaccination.

d. The national standard of practice for all immunizations, including the smallpox vaccine, shall be adhered to when immunizing personnel. This includes medical screening prior to immunization. Screening shall be conducted for medical conditions for which immunization deferral or further medical evaluation before immunization is indicated.

e. Per AR 600-110, live virus vaccines such as smallpox vaccine may be administered to military personnel provided there is a record of a negative HIV test within the previous 24 months. HIV testing is not mandatory for civilian personnel, but may be performed as indicated by medical screening, and evaluation in a military medical treatment facility for this purpose.

f. Healthcare professionals and staff play key roles in this program, both in its execution as well as providing expert advice to soldiers, civilians, and commanders. They must become familiar with key aspects of smallpox (variola virus) disease and the smallpox (vaccinia) vaccine. All must read the package insert (Ref. G this ANNEX) and be familiar with the informational briefings referenced at Appendices 3 and 4 ANNEX E and the additional resources at Appendices 5 and 6. These will be crucial in communicating to the troops that the vaccine is safe and effective, if used properly. Healthcare providers will remain alert to modifications in clinical recommendations as the SVP continues. Such changes will be posted at http://www.smallpox.army.mil/.

g. Medical personnel must understand the potential adverse events that are possible after smallpox (vaccinia) vaccination. They must know how to minimize them, how to respond to them and report them IAW Part 8 this ANNEX. Medical personnel will not only administer the vaccine, but will likely be the "front line," responding to vaccine recipients' questions and concerns. Medical personnel must treat each concern with care. Some symptoms following smallpox (vaccinia) vaccination may or may not be caused by the vaccination, but all deserve individual attention.

h. Before beginning smallpox vaccinations at any installation, preventive medicine (PM) staff will contact their counterparts at city, county, and state public health departments to inform them that smallpox vaccinations will begin in the near future. PM staff may inform them of a rough order of magnitude of number of vaccinations to be carried out, but need not inform them of unit names or duties.

PM staff may describe staff training procedures, servicemember education, and efforts to prevent auto-inoculation and contact transfer of vaccinia virus to others.

6. MEDICAL EXEMPTIONS FROM SVP.

a. Some individuals will have either acute or chronic pre-existing conditions that may warrant medical exemption from smallpox vaccination. In some cases, vaccination should be withheld if the individual cannot avoid household contact with another person with contraindicating conditions. Furthermore, a small proportion of individuals will develop a more serious reaction that may warrant medical exemptions, temporary or permanent, from further smallpox vaccination.

b. In a smallpox emergency, there are no absolute contraindications regarding vaccination of a person with a high-risk exposure to smallpox. People at greatest risk for experiencing serious vaccination complications are often those at greatest risk for death from smallpox. If a relative contraindication to vaccination exists, the risk for experiencing serious vaccination complications must be individually weighed against the risk for experiencing a potentially fatal smallpox infection.

c. Granting medical exemptions is a medical function only to be performed by a privileged DoD health-care provider (specifically, a physician, physician assistant, nurse practitioner). The provider will grant individual exemptions when medically warranted, with the overall health and welfare of the patient clearly in mind, balancing potential benefits with the risks while taking into consideration the threat situation.

d. The two most common medical exemptions utilized are medical temporary (MT) or medical permanent (MP). Annotate the patient's Health Record and record in the MEDPROS immunization tracking system these codes, and update them as appropriate. In the event of a confirmed smallpox outbreak, permanent exemptions could be lifted, based on individual risk.

e. People who have household contact with a person vulnerable to vaccinia virus (e.g., immune-suppressed people, people with atopic dermatitis or eczema, pregnant women) shall either have alternate housing arrangements or be exempted from smallpox vaccination until the household-contact situation is no longer applicable. Scheduling vaccinations just before or during 21-day deployments or family separation is another option. This avoidance of contact should continue until the vaccination scab falls off on its own. Note that this contact relates to household contacts, not to family members per se. The risk is that of contact transfer of vaccinia virus. In a barracks or similar military setting, the only major concern involves close berthing situations, described below.

f. Military-unique berthing settings require similar precautions. Exempt individuals should be physically separated and exempt from duties that pose the likelihood of contact with potentially infectious materials (e.g., clothing, towels, linen) from recently vaccinated people. This separation will include not having the vaccine recipient share sleeping or close living space (e.g., the same cot, bunk, berth, mattress, sleeping bag) with susceptible people. Close occupational settings (e.g., vehicles, tanks, aircraft) are not affected, if due attention is given to simply covering the vaccination site with Band-Aids and sleeves.

g. Temporary medical exemptions are warranted when a provider has a concern about the safety of continued immunizations. Examples of situations that warrant a temporary medical exemption appear in the vaccine's package insert (e.g., immune-suppressed people, pregnant women). The ACIP notes that people with other acute, chronic, or exfoliative skin conditions (e.g., atopic dermatitis, burns, impetigo, or varicella zoster, herpes, psoriasis, severe or uncontrolled acne) may also be at higher risk for eczema vaccinatum and should not be vaccinated until the condition resolves.

h. In situations where a medical condition is being evaluated or treated, a temporary deferral of smallpox vaccination may be warranted, up to 12 months. This would include significant vaccine-associated adverse events that are being evaluated or while awaiting specialist consultation. The attending physician will determine the deferral interval, based on individual clinical circumstances.

i. Medical permanent (MP) exemptions are generally warranted if the medical condition or adverse reaction is so severe or unremitting that, the risk of subsequent immunization is not justified. In the case of smallpox vaccine, these permanent exemptions could be lifted if the individual had prolonged face-to-face contact with someone in the contagious phases of smallpox. Examples of situations otherwise warranting a permanent medical exemption appear in the vaccine's package insert (e.g., life-threatening allergy to a vaccine component, immune-suppressed people, people infected with human immunodeficiency virus, people with atopic dermatitis or eczema or a past medical diagnosis of eczema). People with contraindicating skin conditions who received smallpox vaccine earlier in life may be revaccinated after medical consultation for individual risk-benefit decision-making.

j. If an individual's clinical case is complex or not readily definable, consult an appropriate medical specialist with vaccine safety assessment expertise, before a permanent medical exemption is granted. In addition, the original health care provider may consult with physicians working with the Vaccine Healthcare Center Network. Medical records will be accurately and appropriately annotated pertaining to any temporary or permanent medical exemptions. When no longer clinically warranted, medical exemptions will be revoked.

k. If a patient disagrees with an initial medical decision or diagnosis, he or she may request a second opinion at the next higher military medical treatment facility. If the second opinion is one with which the patient again disagrees, he, or she may be referred directly to the Vaccine Healthcare Center Network.

l. Each military treatment facility will assist people in obtaining appropriate specialty consultations expeditiously and assist in resolving patient difficulties. Specialists, (who are privileged healthcare providers, specifically a physician, physician assistant, or nurse practitioner) may grant permanent medical exemptions. Return of the patient to his or her DoD primary-care provider is not required if the referring specialist deems a permanent medical exemption is warranted. The following medical exemption codes relate to all vaccines. File a Vaccine Adverse Event Reporting System (VAERS) report for any permanent medical exemption due to a vaccine related adverse event.

m. Medical Exemption Codes.

Code	Meaning	Explanation or Example	Duration
MP	Medical, Permanent*	1. Diseases or conditions that cause immunodeficiency or immunosuppression in vaccinee: e.g., HIV/AIDS, solid organ or stem cell transplant, generalized malignancy, leukemia, lymphoma, agammaglobulinemia. 2. Previous severe allergic reaction to smallpox vaccine or to any vaccine component (polymyxin-B sulfate, dihydrostreptomycin sulfate, chlortetracycline hydrochloride, neomycin sulfate, latex in stopper). 3. People who have ever been diagnosed with eczema or atopic dermatitis. 4. Treatments that cause chronic immunodeficiency or immunosuppression in vaccinee: e.g., treatment with radiation, antimetabolites, alkylating agents, corticosteroids, chemotherapy agents, or organ transplant medications.	Indefinite
MI	Medical, Immune	Evidence of immunity. 1. For clinical smallpox, documented infection (indefinite exemption). 2. Documented confirmed take in medical records within the past 5 years after primary vaccination or 10 years after revaccination.	10 years
MT	Medical, Temporary	1. Age less than 12 months. 2. During pregnancy, suspected pregnancy, or to household contacts of pregnant women. Also during breastfeeding. 3. Hospitalization, convalescent leave, moderate or severe acute illness. 4. Treatments or medical conditions that cause temporary immune suppression. 5. Vaccinee has household or other intimate contact with someone who would personally be exempted from vaccination due to a medical condition. 6. If vaccinee or household contacts have acute, chronic, or exfoliative skin conditions, e.g. wounds, burns, impetigo, chickenpox, shingles, herpes, uncontrolled acne, psoriasis, they are at risk for auto-inoculation and should not be vaccinated until the condition resolves. 7. Any temporary contraindication to immunization.	Specified period
MD	Medical, Declined	Declination of optional vaccines, religious waivers.	Indefinite
MS	Medical, Supply	Exempt due to lack of vaccine supply.	Indefinite
MR	Medical, Reactive	Severe adverse reaction after immunization (e.g., anaphylaxis). Code can be reversed if an alternate form of prophylaxis is available. Always warrants a VAERS report, when case is contemporary and data exists to complete the VAERS report. In the cases where MR exemption is granted and documented based on patient's past medical history of severe adverse reaction to this vaccine, sufficient data may not be available to file a VAERS report.	Indefinite

7. EXPECTED REACTIONS.

a. In a nonimmune person who is not immunosuppressed, the expected response to primary vaccination is the development of a papule at the site of vaccination 2-5 days after administration. The

papule becomes vesicular; the pustule usually reaches it maximum size in 8-10 days. The pustule dries and forms a scab, which separates in 14-21 days after vaccination, leaving a scar.

b. As with any vaccine, some individuals receiving smallpox vaccine will experience side effects or adverse events. Adults vaccinated for the first time may develop a clinical illness with injection-site inflammation, muscle aches, and fatigue, most often on days eight to nine after vaccination. In rare instances, smallpox vaccine exhibits a unique, more severe adverse-event profile including encephalitis, progressive vaccinia, eczema vaccinatum and other conditions.

c. DoD Clinical Guidelines for Management of Adverse Events After Vaccination offer useful advice. These guidelines are available at Refs d, e and h of this ANNEX. Specific guidance for management of adverse reactions unique to smallpox vaccination will be published at a later date.

d. Specific information about treatment with vaccinia immune globulin (VIG) appears in the DoD Smallpox Response Plan and in ACIP recommendations. In summary, VIG is available under investigational new drug (IND) protocol to treat progressive vaccinia, eczema vaccinatum, severe generalized vaccinia and severe ocular vaccinia. Providers may request use of VIG for a named patient by telephoning the U.S. Army Medical Research Institute of Infectious Diseases at 1-888-USA-RIID (1-888-872-7443) 24 hours a day. Additionally, after duty hours, one can call the USAMRIID Security Desk at 301-619-2257, or page the USAMRIID staff duty officer at 301-631-4393. IND-specific procedures must be followed carefully.

8. ADVERSE-EVENT RECORDING AND REPORTING.

a. Document all significant adverse events in the individual's health record. Mandatory information for adverse-event reporting consists of identification of the vaccine, the lot number and manufacturer, the date of administration, the name and location of the medical facility, the type and severity of the event. In addition to recording the event in the health record, all adverse vaccine events resulting in death, hospitalization, or more than 24 hours lost from duty must be reported to the Vaccine Adverse Events Reporting System (VAERS). Reports must also be filed for cases of auto-inoculation or contact transfer. Further, the patient or healthcare provider is encouraged to report other adverse events that in the provider's professional judgment appear to be unexpected in nature and severity. Submission of a VAERS report is not an indictment against the vaccine, vaccine administrator, health care facility, chain of command, or an individual. It simply facilitates review of temporally associated conditions and adds to the safety database on the vaccine.

(1) Medical personnel will submit VAERS reports to the supporting USAMEDCOM MTF. Online reporting to www.vaers.org is encouraged, to facilitate data entry and review by the VAERS staff. Print out copies of these reports to the MTF Pharmacy and Therapeutics Committee for review.

(2) The Chairman, MTF Pharmacy and Therapeutics Committee, will submit reports to the FDA's Vaccine Adverse Event Reporting System, PO Box 1100, Rockville, MD 20849-1100, if not already reported (See ANNEX A, references 2 and 3; Ref. f this ANNEX).

(3) The Chairman, MTF Pharmacy and Therapeutics Committee will also provide a copy of the VAERS report to the Reportable Disease Project Officer at the Army Medical Surveillance Activity (AMSA), U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM), Building T-20, Walter Reed Army Medical Center, Washington, DC 20307-5100, DSN 662-04741 or commercial 202-782-0471. Reportable adverse events will also be reported to AMSA, through the MTF preventive medicine activity, using the automated reportable events system.

(4) VAERS forms are available directly from the Internet at the website referenced at Ref h this ANNEX or can be obtained by calling 1-800-822-7967, Monday – Friday, 0800 – 1700 ET.

(5) A VAERS report should be filed for any permanent medical exemption due to a vaccine-related adverse event.

b. Adverse event reports from National Guard and Army Reserve units will be filed through command channels to the appropriate ARNG State Area Command (STARC) or Army Reserve intermediate headquarters—Reserve Support Command (RSC), 7th Army Reserve Command (7th ARCOM), U.S. Army Special Operations Command (USASOC), or Army Reserve Personnel Command (AR-PERSCOM), as applicable—to the appropriate AMEDD Regional Medical Command (RMC). The RMC will ensure an appropriate Pharmacy and Therapeutics Committee reviews the reports and forwards them IAW Part 8.a.

c. USACHPPM will also receive consolidated adverse event reports from each Service through the Defense Medical Surveillance System (DMSS) and provide quarterly status reports to USAMEDCOM.

9. CONTRAINDICATIONS AND PRECAUTIONS.

a. Contraindications.

(1) Individuals receiving therapy with systemic corticosteroids or immunosuppressive drugs such as alkylating agents, antimetabolites, or radiation, or if household contacts are receiving such therapies.

(2) Immunodeficiency diseases such as AIDS, cancer, agammaglobulinemia, or household contacts of such individuals.

(3) Life-threatening allergies to polymyxin B sulfate, dihydrostreptomycin sulfate, chlortetracycline hydrochloride, neomycin sulfate, or latex (from the stopper).

(4) Individuals of any age with atopic dermatitis or eczema or past history of atopic dermatitis or eczema, or for those whose household contacts have atopic dermatitis or eczema, or acute, chronic, or exfoliative skin conditions, such as atopic dermatitis, wounds, burns, impetigo, varicella zoster, or uncontrolled acne or psoriasis, and for household contacts of such individuals.

(5) Women who are pregnant, or household contacts of pregnant women.

(6) Breast-feeding women.

b. Precautions.

(1) Routine immunization precautions against allergic and anaphylactic reaction should be followed IAW AR 40-562. Personnel with a history of latex sensitivity should be referred for medical advice, because the vial stopper contains dry natural rubber. All personnel should be observed for 15 minutes or longer for any sign of hypersensitivity reaction.

(2) Defer immunization for any person with an active infection with fever. Persons with moderate or severe acute illness should also defer vaccination until recovery (MT).

(3) The vaccine vial, its stopper, the needle to release the vacuum, the diluent's syringe, the vented needle used for reconstitution, the bifurcated needle used for administration, and any gauze or cotton that came in contact with the vaccine should be burned, boiled, or autoclaved before disposal.

(4) Because the risks of smallpox vaccine in HIV infected individuals are not completely known, smallpox vaccine should not be given to HIV infected individuals in routine, non-emergency conditions. There are no data on the safety or effectiveness of smallpox vaccine in HIV-infected individuals.

(5) Vaccinia virus may be cultured from vaccination site 2 to 5 days after vaccination and until scab separates from the skin lesion 14 to 21 days after vaccination. During this time, care must be taken to prevent spread of virus to another area of the body or to another person.

(6) Recently vaccinated healthcare workers should minimize contact with unvaccinated patients, particularly those with immunodeficiencies until the scab falls off. The vaccination site must be well covered and good hand-washing technique is essential by the vaccinee to protect patients.

(7) Pregnancy, Breastfeeding, & Infant Care.

(a) Because the risks of smallpox vaccine in pregnancy are not completely known, smallpox vaccine should not be given to pregnant women in routine, non-emergency conditions. All immunization clinics will display in a prominent place written warning against unintentionally vaccinating pregnant women. This warning must be visible during the screening process. To ensure that pregnant women are not immunized inadvertently, the following procedure will be followed:

1 Before immunization, each woman of child-bearing age will be provided information concerning immunizations and pregnancy. In addition to general information on this topic, specific information on the vaccine will be provided.

2 Provided with this information and the opportunity to read it, each woman will be asked if she is pregnant or could be pregnant.

3 Each woman will be asked if she would like to have a test performed to confirm a possible pregnancy. A urine pregnancy test is sufficient for verification.

4 Each woman and the medical personnel conducting the interview will document the interview by initialing and dating the general information. The sheet will be maintained in the woman's medical record.

5 If the woman states that she is not pregnant or if she is found not to be pregnant on testing, then she will be immunized.

6 If a pregnancy test is requested by the woman, immunization will be deferred until a pregnancy test is completed. If the test is positive, immunization will only be given if clinically indicated.

(b) On rare occasions, almost always after primary vaccination, vaccinia virus has been reported to cause fetal infection. Fetal vaccinia usually results in stillbirth or death of the infant shortly after delivery. Vaccinia vaccine is not known to cause congenital malformations. Any episodes of immunization with smallpox vaccine during pregnancy must be documented in the woman's medical record.

(c) Advise women to avoid pregnancy for 4 weeks after smallpox vaccination, to avoid any hypothetical risk of problems very early in pregnancy.

(d) Breast-feeding (lactation). It is not known whether vaccine antigens or antibodies are excreted in human milk. Breast-feeding may place an infant in close proximity to the mother's vaccination site, increasing the risk of contact transfer of vaccinia virus. The vaccine is not recommended for use in a nursing mother in non-emergency conditions.

(e) People with infants less than 1 year old in the household should be vaccinated only if alternate care-giving arrangements are observed until the scab falls off.

(8) Blood donations. Because there is a significant donor deferral period associated with smallpox vaccination, it is critical that vaccination schedules be closely coordinated with local military and civilian donor center collections schedules to reduce the impact on the readiness and availability of the military blood supply. Individuals who receive the vaccination, and have no complications, will be deferred from donating blood until the scab spontaneously separates (14-21 days after vaccination). In cases where a scab is otherwise removed, the donor may be deferred for two months after vaccination. Individuals with vaccine complications will be deferred until 14 days after all vaccine complications have completely resolved.

10. The points of contact for this ANNEX are as follows:

a. Administrative Issues—MILVAX Agency, 1-877-GET-VACC, http://www.smallpox.army.mil/.

b. Medical Record Keeping Issues—OTSG Health Policy and Services, Patient Administration Division, 703-681-3106, DSN—761-3106.

c. Pre-vaccination Requirements--the Preventive Medicine Staff Officer at Office of The Surgeon General, HQDA, ATTN: DASG-HS-PM, DSN 761.3160; COMM (703) 681-3160.

d. Medical Exemption Issues-- MILVAX Agency, 1-877-GETVACC, http://www.smallpox.army.mil

e. Expected and Unexpected Adverse Events After Vaccination—Walter Reed National Vaccine Healthcare Center, (202) 782-0411, or DSN: 662-0411, http://www.vhcinfo.org/.

f. Adverse Event Recording and Reporting, the Preventive Medicine Staff Officer at Office of The Surgeon General, HQDA, ATTN: DASG-HS-PM, DSN 761.3160; COMM (703) 681-3160.

g. Contraindications and Precautions, MILVAX Agency—1-877-GET-VACC, http://www.smallpox.army.mil/.

APPENDIX 1 to ANNEX C (MEDICAL CONSIDERATIONS AND GUIDANCE)

OPTIONS FOR VACCINATING PERSONNEL OTHERWISE MEDICALLY EXEMPT BECAUSE OF HOUSEHOLD CONTACTS

1. Situation.

a. A person is eligible for smallpox vaccination due to duty assignment and medical history. However, even if the person to be vaccinated may not have a personal medical history contraindicating vaccination (e.g., eczema, immune-suppression, pregnancy) per Annex C, para 6, that person may have a household contact (e.g., spouse, child) who has a medical contraindication related to the vaccinia virus within smallpox vaccine. By DoD clinical policy dated 26 Nov 02 (http://www.smallpox.army.mil/media/pdf/SPclinicalpolicy.pdf):

> "People who have household contact with a person who has a contraindication to smallpox vaccination (e.g., immune-suppressed people, people with atopic dermatitis or eczema, pregnant women) shall either have alternate housing arrangements or be exempted from smallpox vaccination until the household-contact situation is no longer applicable. Scheduling vaccinations shortly before or during 21-day or greater deployments or family separation is an option. This avoidance of contact should continue until the vaccination scab falls off on its own."

b. The hazard to avoid is the spread of vaccinia virus from the vaccination site to another person by inadvertent contact, either directly or by means of clothing, towels, sheets, or similar items that could transfer the virus. Historically, the rate of spread of vaccinia virus to contacts was quite rare, about 27 cases per million vaccinations, mostly in households. But DoD's goal is to reduce the risk as much as possible.

2. Commanders' Responsibility.

a. Commanders will actively manage their personnel who are temporarily medically exempt from smallpox vaccination due to a household contact who has a medical contraindication and ensure their vaccination when that household contact exemption no longer applies. Commanders basically have two options, either (1) arrange for alternate housing from day of vaccination until the vaccination scab falls off (about 14-21 days), or (2) vaccinate the person when the exemption no longer applies (e.g., after family separation during mobilization or at time of deployment).

b. Unacceptable. Permitting a vaccine recipient to reside in a house, trailer, apartment, or similar household with a medically exempt contact is unacceptable, until the scab falls off. Similarly, having a smallpox vaccine recipient share sleeping space (e.g., same cot, bunk, berth, mattress, sleeping bag) with medically exempt people is unacceptable. Close occupational settings (e.g., vehicles, tanks, aircraft) are not affected by these exemptions, if due attention is given to simply covering the vaccination site with Band-Aids® and sleeves.

c. Acceptable.

(1) Vaccinating the person when the exemption no longer applies is acceptable. Commanders can manage their roster of temporary medical exemptions due to household contacts and vaccinate those personnel after family separation, during mobilization or at time of deployment.

(2) Having the vaccinated servicemember use alternate lodging (e.g., barracks, dormitory room, tents) on a military installation, vessel, or aircraft, or in contracted space is acceptable. Funding for contracted space is not available centrally, but must be funded by local commands. This arrangement physically separates the servicemember from the exempted household contact.

(3) Having the vaccine recipient voluntarily arrange for alternate lodging in privately-owned or managed space is acceptable, if the unit commander has a reasonable expectation that the vaccine

recipient will comply with the requirement to not share living space with a medically exempt household contact. For example, a male soldier (family #1) can move in temporarily with another male soldier (family #2) in the home of family #2, while one wife (family #2) moves in with the other wife (family #1) in the home of family #1.

(4) The vaccine recipient can continue to have reasonable access to a medically exempt household contact, so long as the access includes careful hand-washing and does not involve extensive physical contact or contact involving clothing, sheets, towels, or other items likely to transfer vaccinia virus.

(5) Normal barracks situations in which vaccine recipients share living spaces such as common latrines, bedrooms, kitchens, and TV or game rooms is acceptable. Recipients do not typically experience the close day to day physical contact associated with an intimate family situation. Care should be taken, so recipients do not share towels or linens in a barracks situations; they should do their own laundry. Vaccine recipients living in barracks should follow routine site care instructions—simply covering the vaccination site with Band-Aids® and sleeves—to avoid spread of the vaccinia virus.

APPENDIX 2 to ANNEX C (MEDICAL CONSIDERATIONS AND GUIDANCE)

12-STEP APPROACH TO SMALLPOX VACCINATION

1. Space. Plan for:

a. classroom or auditorium space for briefings,

b. smaller, more private space(s) for vaccine candidates to ask questions of clinicians about their personal situation,

c. clinic space for vaccine delivery and documentation. See also Annex B of the DoD Smallpox Response Plan, ANNEX A, Ref 11.

2. Supplies & Logistics. Vaccine kits come with 100 bifurcated needles each. Plan separately for hand sanitizers, cleansing supplies (e.g., soap, acetone, alcohol, disinfectants), 2x2 sterile gauze, 4x4 sterile gauze, 2x3 Telfa gauze, Micropore, Transpore, Scanpore tape, semi-permeable membrane bandages for healthcare workers, standard Band-Aids® for other vaccine recipients, gloves, rigid sharps containers, biohazard bags, extra bifurcated needles for training, tape-glue remover, paper rulers, forms, et cetera.

3. Identify Teams, Team Leaders, & Clear Division Of Responsibilities. Establish methods for communication. Plan regular meetings. Establish email groups to share new information or changes to plan rapidly. Define prescribing authority to administer the vaccine. Identify expeditious pathways for clinical consults (e.g., cell-phone access to dermatologists or other specialists by primary-care providers screening vaccine candidates). Before initiating smallpox vaccinations, flight surgeons should record background rates of “duties not including flying” (DNIF) among aviators, to determine effects of smallpox vaccination on DNIF rates.

4. Train Medical & Support Personnel Thoroughly. Provide smallpox-specific training for medical director, clinical consultants, vaccination supervisors, vaccinators (see education toolkit at www.smallpox.army.mil for training presentations; via CD-ROM in remote locations), administrative team, logistics team, information management team, patient-administration team, laboratory-support team. Agree on scope of practice for each professional and paraprofessional category of worker. Review emergency procedures for fainting, anaphylaxis, other acute events, need for vaccinia immune globulin. Clinicians need to be familiar with DoD clinical policies at: http://www.smallpox.army.mil/media/pdf/SPclinicalpolicy.pdf. Speakers must be well versed in smallpox and vaccinia details (at a minimum, be fluent in the questions and answers at www.smallpox.army.mil, resource center).

5. Public Relations. Notify city, county, and state or host nation health department that vaccinations are about to begin. Prepare press release for local news media. Permit access to knowledgeable spokesperson, but do not allow media to disrupt clinic flow. Media may take photographs of vaccination; however, IAW DoD Public Affairs Guidance **DO NOT** allow photographs that identify the soldier/civilian or unit involved. Coordinate with installation public-affairs outlets (e.g., installation newspaper).

6. Educate Vaccine Candidates & Their Family Members & Close Contacts. Provide briefings on smallpox, smallpox vaccine, risks, benefits, issues regarding site care, and ways to prevent auto-inoculation and contact transfer of vaccinia (use current briefing slides at www.smallpox.army.mil, educational toolkit). Permit ample time to answer questions. Ideally, hold education and medical screening events at least the day before vaccination day, to allow time for questions to be answered. Distribution of current DoD Smallpox Trifold Brochure is required (see www.smallpox.army.mil, educational toolkit); your local medical treatment facility has stocks of these for use. Distribution of CDC’s Smallpox Vaccine Information Statement (VIS) is recommended. Thirty-day diary cards are available for use, if desired individually or collectively.

7. Answer Vaccine Candidates' Individual Questions. Expect questions to arise after briefing sessions, after vaccination, up through healing of vaccination sites. Provide ready access to healthcare providers to decipher memories of childhood health conditions.

8. Medical Screening Process. Use current version of DoD standard screening forms ("Initial Medical Notes") at www.smallpox.army.mil, resource center, forms). Two- and three-page versions are available, according to clinic preference. Have physician, physician assistant, or nurse practitioner on site during screening to resolve questions about diagnoses and contraindications (especially regarding eczema and atopic dermatitis), to order medical consults, and to determine fitness for smallpox vaccination. Remind medical personnel to accept an oral history of prior smallpox vaccination, supplemented with records or evidence of an earlier vaccination scar. Presumptive evidence includes birth before 1971 (i.e., 1 year of age in 1972) or military entry before 1990.

9. Vaccination.

a. Deliver all jabs (punctures) as close together in space and time as possible. Educate vaccinators to validate the procedure by immediate inspection of vaccination site, looking for trace bleeding or bleeding beneath the skin (petechiae). Vaccinators should avoid inducing frank bleeding (suggesting excess force). If no evidence of skin-surface break (e.g., trace bleeding, petechiae) within ~20 seconds, revaccinate immediately. Walter Reed Army Medical Center used a skin marker to place four dots in a 1-cm diameter circle, with all jabs placed between these aiming points.

b. At the vaccination station, use a team of two vaccinators who trade off duties. One administers the vaccination jabs, while the other acts as blotter, bandager, and documenter. Have additional staff assure completeness of all forms.

c. Locate the vial of smallpox vaccine toward the back of the vaccination station, so that items are not passed over an open vial. A hole may be carved in a Styrofoam block, to prevent the small vial from being accidentally bumped and spilled. During prolonged vaccination sessions, place the vial on a cooling (but not freezing) tray.

10. Post-Vaccination Care.

a. Remind vaccine recipients of importance of not touching vaccination site and using barriers (e.g., Band-Aids, sleeves) and hand washing to prevent auto-inoculation and contact transfer. Instruct vaccine recipients about expected vaccination response. Instruct them where to return for response evaluation. At "take-check" visits, use common DoD form to evaluate response and identify symptoms after vaccination (current versions are available at www.smallpox.army.mil/resource/forms.asp).

b. Use WHO/CDC definitions for major reaction ("take") and equivocal reactions. See www.smallpox.army.mil/media/pdf/SPclinicalpolicy.pdf or paragraph 2.b.(4), ANNEX C this plan.

c. For healthcare workers: Per DoD policy, each DoD hospital and clinic will establish a bandage-checking station, to evaluation bandage integrity at beginning of each worker's duty shift. Replace bandages when the absorbent pad collects exudate (e.g., every 2 to 3 days). With adequate attention to infection control and bandage assessment, there is no need to furlough medical workers. A restriction on hands-on care in transplantation and oncology wards and neonatal nurseries may be prudent.

11. Adverse Events. Assure primary-care clinics are alert to expected and unexpected adverse events after smallpox vaccination. Fever-malaise-lymphadenopathy syndrome may peak 8 to 12 days after vaccination, with greater incidence among primary vaccinees than after revaccination. Refer patient as needed for diagnosis, treatment and follow-up. Report events to the Vaccine Adverse Events Reporting System (VAERS) that involve hospitalization, loss of duty >24 hours, auto-inoculation, or contact vaccinia transfer. Encourage filing VAERS reports online via www.vaers.org, with paper copies submitted via usual reporting channels.

12. Quality Assurance.

a. Confirm adequacy of screening for people with personal or household contraindications to smallpox vaccination. Track the take rate of the first 50 to 100 people vaccinated by each vaccinator, to assure proper technique. Reinforce instructions for bandages, sleeves, and hand washing, to prevent auto-inoculation and contact transfer of vaccinia virus. Confirm proper vaccine storage and handling. Look for differences in take rate or infection rate with one vial, compared to others.

b. Audit quality of entries into electronic immunization tracking systems (e.g., MEDPROS, AFCITA, SAMS) against paper-based immunization records. Emphasize precision of entry for name of vaccine, date of vaccination, lot #, and provider.

Source: Lessons learned at Walter Reed Army Medical Center, Dec 02 – Jan 03.

ANNEX D - LOGISTICS

1. PURPOSE. To provide the logistics concept of operations for the Smallpox Vaccination Program.

2. GENERAL INFORMATION. The following information on smallpox (vaccinia) vaccine is provided:

a. NSN: 6505-00-903-8173.

b. Nomenclature: Smallpox Vaccine Vaccinia (Dryvax®) full-strength.

c. Unit of Issue: 100-dose vial with diluent, 100 bifurcated needles, and 100 transfer needles.

d. Shelf life: up to 60 days after reconstitution, studies underway may justify longer use after reconstitution. See www.smallpox.army.mil for updates on this topic.

e. Storage: Store product at 2 to 8 degrees C (36 - 46 degrees F). DO NOT FREEZE.

f. Acquisition Advice Code: A

g. Cost: The smallpox vaccine will be provided through USAMMA at no cost to units. Ancillary supplies are the responsibility of the receiving activity (see Part 5 for recommended ancillary supplies). The current contract includes manufacturer distribution to first destination. Transportation will be conducted by a commercial freight forwarder for all destinations.

3. CONCEPT OF OPERATION. Logistics Overview.

a. The U.S. Army Medical Materiel Agency (USAMMA) will coordinate the allocation and distribution of the smallpox vaccine with the Military Vaccine Office.

b. The vaccine is centrally funded by the Program Executive Office for Chemical and Biological Defense (PEOCBD)--formerly Joint Program Office for Biological Defense (JPO-BD). The vaccine is not a Defense Supply Center Philadelphia, stocked item; therefore, requisitions for the vaccine will be submitted off-line to United States Army Medical Materiel Agency (USAMMA). USAMMA has web-based ordering capability (http://www.usamma.army.mil/) Notified units will submit their initial requisition for a 60-90 day supply requirement. Units must make plans for submitting their subsequent requisitions of vaccines at 90-day intervals (with sufficient order ship times).

c. When a requisition for the vaccine has been validated by Services and approved by the Military Vaccine Office, USAMMA will forward the requisition to the Centers for Disease Control and Prevention (CDC) National Pharmaceutical Stockpile (NPS). NPS will distribute smallpox vaccine, in coordination with USAMMA, to the requesting activity.

4. RESPONSIBILITIES.

a. Office of the Surgeon General (OTSG)/U.S. Army Medical Command, Military Vaccine Office.

(1) Oversight for the Smallpox Vaccination Program.

(2) Management of the distribution of vaccine worldwide.

(3) Validation of off-line requisitions from units against the HQDA unit priority lists.

b. U.S. Army Medical Materiel Agency.

(1) Coordinate the release of vaccine with National Pharmaceutical Stockpile.

(a) Number of vials to be released.

(b) Address of ship-to activity (because commercial carriers will be used, street, specific building/room number, POC, and phone number must be provided for each shipment; no PO boxes or APO/FPOs).

(2) Coordinate the receipt of vaccine with the activity.

(3) Provide the activity advanced shipping information.

(4) Provide the activity authorization/release of vaccine for use. If immediate release of vaccine is necessary the receiving activity is required to contact USAMMA and follow "green light/red light" instructions. (Ref. APPENDIX A this ANNEX)

(5) Provide the activities vaccine redistribution instructions for vaccine when required. (Ref. Appendix B)

(6) Provide the activities disposition instructions for vaccine when required. (Ref. APPENDIX C this ANNEX)

c. Installation Medical Supply Activities (IMSAs)/Medical Logistics Battalions.

(1) Receive and forward off-line requisitions (via USAMMA web site) from supported units. Requisitions forwarded to USAMMA will include the following:

(a) Number of vials requested.

(b) Justification (in a secure environment).

(c) Requestor (IMSA) Info: POC, phone number, fax number.

(d) Servicing Regional Medical Command (RMC).

(e) Ship to Address (including building/room number).

(f) Ship to POC Info: POC, phone number, email address, alternate POC, alternate phone number, alternate email address, fax number.

(2) If the IMSA is the ultimate destination:

(a) Establish due in for the vaccine.

(b) Notify USAMMA POC upon receipt of vaccine with the following data:

1 Receipt of vaccine.

2 Number of vials received by lot number.

3 Condition of vaccine.

4 Shipment discrepancies (i.e., incorrect quantity, damaged shipment, etc.), if applicable.

5 Airway bill tracking number for return of temperature monitor(s).

(c) Return the temperature control monitor(s) to USAMMA, 1423 Sultan Drive, Suite 100, Fort Detrick, MD 21702-5001, in provided FEDEX/DHL envelopes.

(d) Once released by USAMMA, vaccine may be administered by immunization personnel.

(3) Maintain records reflecting quantities, lot numbers, and units to which the lots were distributed.

(4) Provide supply status reports to your RMC, Medical Command, or chain of commands as required.

d. If unit is ultimate destination.

(1) Submit requests for vaccine via IMSA/MEDLOG BN. The IMSA/MEDLOG BN will submit off-line requisitions through the USAMMA web site. Requisitions forwarded to USAMMA will include the following:

(a) Number of vials requested.

(b) Justification.

(c) Requestor (IMSA) Info: POC, phone number, fax number.

(d) Servicing Regional Medical Command (RMC).

(e) Ship to Address (including building/room number); Ship to POC Info: POC, phone number, email address, alternate POC, alternate phone number, alternate email address, fax number.

(2) Establish due in for the vaccine.

(3) Notify USAMMA POC upon receipt of vaccine with the following data:

(a) Receipt of Vaccine.

(b) Number of vials received by lot number.

(c) Condition of vaccine.

(d) Shipment discrepancies (i.e., incorrect quantity, damaged shipment, etc.), if applicable.

(e) Airway bill tracking number for return of temperature monitor(s).

(4) Return the temperature control monitor(s) to USAMMA, 1423 Sultan Drive, Suite 100, Fort Detrick, MD 21702-5001, in provided FEDEX/DHL envelopes.

(5) Once released by USAMMA, vaccine may be administered by immunization personnel.

(6) Maintain records reflecting lot numbers and quantities.

(7) Provide supply status reports to your RMC, Medical Command, or chain of command as required.

(8) Submit requisitions for ancillary supplies to IMSA/MEDLOG BN.

(9) Schedule subsequent off-line requisitions of vaccine at 90-day intervals (allow for order-ship time).

5. ANCILLARY SUPPLIES. The following is the preferred list of ancillary supplies for the administration of smallpox vaccine:

NSN	ITEM	U/I
6510-00-786-3736	Cotton, isopropyl (alcohol pad)	100s
6510-00-782-2700	Sponge gauze 2X3 inch (gauze)	
	Gloves	
	Sharps container	

NOTE: It is expected that resuscitative equipment will be in the immediate vicinity where immunizations are administered. A capability to administer immediate first aid and medical care in the event of an anaphylactic or other allergic reaction will exist at all immunization sites per AR 40-562, paragraph 4.4.

6. SUPPORTING EQUIPMENT. (Ref. APPENDIX 4 this ANNEX) For routine distribution operations for all Armed Services, USAMMA DOC funds the following equipment. Services and/or units may purchase additional supporting equipment below to augment local capability with organic funds.

4110-01-459-3690	VaxiCool	$3,335.00	ea
6515-01-475-8145	VaxiPac	$152.62	ea
6850-01-475-8133	VaxiSafe	$6.00	ea
	Endurotherm Box		
	TempTale (temperature monitor)		

7. COORDINATING INSTRUCTIONS. USAMMA POCs listed below will serve as points of contact for questions and/or problems experienced at MTFs relative to the requisitioning, shipment of materiel, and supporting equipment issues. Clinical and policy questions should be addressed to the Military Vaccine Office POC listed below.

a. POCs at USAMMA:

(1) USAMMA Distribution Operations Center (formerly Focused Distribution Management Branch) Comm: (301) 619-4121, 4128, 4411, 4318, 4198, 4320 DSN: 343-4121, 4128, 4411, 4318, 4198, 4320, FAX: 343-4468.

(2) Website: http://www.usamma.army.mil/

(3) Deputy Director, SVP Distribution Operations & USAMMA Pharmacy Consultant Comm: (301) 619-4307 DSN: 343-4307.

b. Implementation Plan/Policy POC at MILVAX Office:

Chief Army Analyst, Comm: (703) 681-2848, DSN: 761-2848.

APPENDIX 1 to ANNEX D (LOGISTICS)

TempTale Monitor

The Distribution Operations Center (DOC) has a system in place for immediately checking the validity of the product(s) and for releasing the product(s). The following procedures apply:

- If shipped product(s) is needed immediately, contact the Distribution Operations Center at Commercial # 301-619-4121/4128/4411/4198/4318/4320, DSN 343, before opening box.
- Upon receipt of the shipment, with a person from the DOC on the phone, open the container and remove the packing materials until you reach the TempTale monitor. Remove the monitor from the box.
- When looking at the face of the TempTale monitor, you will notice two light-emitting diodes (LEDs) recessed towards the bottom of the label. One is a red light and the other is a green light.
- Turn the bottom of the TempTale towards you. You will notice two holes. One hole will have a silver ring around it and the other hole will not.
- While observing the lights on the face of the TempTale monitor, insert a pen in the hole without the silver ring.
- One of the lights will flash at you.
- **If the light is Green.** Your shipment has arrived within its temperature range. At this time the DOC will release the product(s) for immediate use.
- Place the smallpox (vaccinia) vaccine or vaccinia immune globulin (VIG) into proper refrigeration, which is between 2° to 8°C (36° to 46°F). Check refrigerator temperatures at least daily. Cidofovir (Vistide) is stored at controlled room temperature (25°C or 77°F), although refrigeration is acceptable.
- **If the light is Red.** Your shipment did not arrive within its temperature range and you will receive further instructions from the DOC.
- Products are NOT released for use until you get approval from the Distribution Operations Center.
- Return the TempTale and any other material that may be requested, back to the Distribution Operations Center.

If the products are not needed immediately and it is an Outside the Continental United States (OCONUS) location, then all that is needed is a check on the lights on the monitor. The DOC will be notified that shipment has been received and a report will be given on the color of the light. Products will not be released until the DOC receives the TempTale monitor back from recipient and downloads the information.

- **Note: Red and Green light check procedures are designed to validate that the temperature of the product was maintained within acceptable ranges during transport.**

APPENDIX 2 to ANNEX D (LOGISTICS)

REDISTRIBUTION
SMALLPOX VACCINE
STANDARD OPERATING PROCEDURE (SOP)

1. GENERAL INFORMATION

a. PURPOSE: This SOP is intended to establish detailed procedures and effective command and control for redistribution of smallpox vaccine (Dryvax®).

b. OBJECTIVES:

(1) To minimize loss due to expiration by redistribution throughout military organizations.

(2) To ensure proper handling techniques and transportation requirements are established for redistribution of smallpox vaccine.

c. APPLICABILITY: The procedures contained herein are applicable to all military activities receiving smallpox vaccine.

2. SMALLPOX VACCINE INFORMATION: The vaccine and VIG must be refrigerated and maintained at temperatures between 2° and 8° Celsius (36° to 46° Fahrenheit). DO NOT FREEZE. Check refrigerator temperatures at least daily.

3. IDENTIFY VACCINE: Failure to identify products that will not be administered prior to expiration cannot be permitted. Units must review forecasted immunizations to determine if they will be able to administer on-hand vaccine prior to its expiration date. Activities must notify the USAMMA Distribution Operations Center (DOC) at least thirty (30) days before the expiration date to permit the redistribution of the products to a site that can use it before it expires. The DOC must be contacted to coordinate the redistribution of vaccine for any distance that requires greater than 45 minutes traveling time.

4. VACCINE TRANSPORTATION REQUIREMENTS: Routine shipments of the products are accomplished via DoD approved packaging and shipping containers. In the event redistribution of the vaccine becomes necessary and is approved by the DOC and the respective service agency; the approved method of accomplishing redistribution is via the use of the VaxiCool® or VaxiPac®. The VaxiCool® is a commercially procured vaccine refrigeration system the U.S. Army Medical Materiel Agency (USAMMA) purchased for transport and short term storage of vaccines for all redistribution missions. The VaxiPac® is a commercially procured patented phase change material (PCM) container designed to maintain vaccine at the appropriate temperature (2° – 8° Celsius). The Service Medical Logistic Field Operating Agencies (FOAs) should have several containers available to accommodate multiple deliveries. The DOC will provide all guidance and written instructions to the activities losing or gaining vaccine.

5. REDISTRIBUTION PROCEDURES:

a. Activities must report supply status monthly to USAMMA. The report will include receipts, issues, lot numbers, expiration dates, quantities, and storage temperature history. If additional reporting is required, it will be so stipulated by the DOC, USAMMA. Guidance for product redistribution can be obtained from the USAMMA website: http://www.usamma.army.mil/smallpox/index.htm

b. Reports can be phoned or faxed to: DOC, USAMMA, ATTN: Mrs. Bonnie Pereschuk, Mr. David Orgler, Mrs. Kandi Barnhart, Ms. Liz Andrews, Mr. Ruben Gueits, or Mrs. Kitty Reese at DSN 343-4121/4128/4411/4198/4318/4320; or (301) 619-4121/4128/4411/4198/4318/4320, FAX x-4468.

c. Smallpox vaccine requires strict logistical tracking as a critical medical materiel item requiring close control (similar to controlled substances). The DOC will provide the losing activity detailed packing instructions for the VaxiCool® or VaxiPac® container or Endurotherm Box; gaining activities will be provided with a receiving and processing matrix for the transported vaccine.

d. An empty VaxiCool® or VaxiPac® container or Endurotherm Box with shipping labels and a serial numbered security seal will be sent to the losing activity. If the container is damaged, refuse receipt and notify DOC immediately with details of refusal.

e. If container is in satisfactory condition, receive and process documents and pack vaccine/products in accordance with instructions provided.

f. With the provided pre-addressed, overnight express-mail label, send the VaxiCool® or VaxiPac® to the gaining unit.

g. Call DOC to confirm overnight express-mail airbill tracking number, and security seal serial number for the shipment.

h. Upon receipt of the vaccine the gaining activity will immediately inspect the VaxiCool® or VaxiPac®, security seal for serial number accuracy and contents for damage. If container contains a TempTale monitor, please confirm with DOC for procedures.

i. If container or contents are damaged, refuse shipment and notify the DOC immediately with details.

j. If container is in satisfactory condition, receive and immediately secure smallpox vaccine in the required refrigerated storage environment (2° to 8° Celsius or 36° to 46° Fahrenheit). **DO NOT FREEZE.** Call DOC to confirm receipt.

k. Process documents and vaccine in accordance with the information provided.

l. **Request commercial carrier to wait for the VaxiCool® or VaxiPac®.** Ship container back to DOC using the provided pre-addressed, overnight, express-mail label.

m. Call DOC to confirm overnight express-mail label tracking number.

n. Establish stock record accountability of product IAW Service regulations.

o. **DO NOT RELEASE THE VACCINE TO END-USER UNTIL AUTHORIZED BY THE DOC.**

6. Points of Contact:

ARMY (Executive Agent)/COAST GUARD
USAMMA Distribution Operations Center (DOC)
DSN 343-4121/4128/4411/4198/4318/4320 or (301) 619-4121/4128/4411/4198/4318/4320
FAX x4468
Bonnie.Pereschuk@amedd.army.mil

AIR FORCE
MSGT (S) Dale Clark:
DSN 343-4172 or (301) 619-4172 or
PAGER (888) 587-9892, FAX x2557
Dale.Clark@Ft-Detrick.af.mil

NAVY and MARINE CORPS
HM1 Victor Inniss

DSN 343-7117 or (301) 619-7117
veinniss@us.med.navy.mil

APPENDIX 3 to ANNEX D (LOGISTICS)

DISPOSITION INSTRUCTIONS FOR SMALLPOX PRODUCTS

1. PURPOSE: To provide guidance and procedures for the proper disposition of compromised or expired smallpox vaccine and the preparation of the Executive Summary and DA Form 3161.

2. REFERENCE: Hazardous and Medical Waste Program, U.S. Army Center for Health Promotion and Preventive Medicine, Aberdeen Proving Ground, MD (USACHPPM), and Military Item Disposal Instructions (MIDI).

3. APPLICABILITY: The procedures contained herein are applicable to all DoD activities receiving any product issued under the DoD Smallpox Response Plan or DoD Smallpox Preparedness and Vaccination Program Implementation Plan.

4. EXECUTIVE SUMMARY (EXSUM) PROCEDURES: DoD Activities are responsible for reporting any loss of smallpox product(s), due to expiration, or loss of efficacy by another means, i.e. exceeding required temperature parameters.

The following EXSUM requirements must be reported in memorandum format:

a. DoD activity will prepare the EXSUM within 24 hours upon discovery of compromised vaccine.

b. No longer than one page in length.

c. Explain the circumstances surrounding the loss of vaccine potency or why the activity did not use the vaccine.

d. Complete list of lot number(s).

e. Complete count of whole vial(s).

f. Detailed explanation of course of corrective action to preclude future losses of vaccine/products.

g. List of names and telephone numbers of points of contacts.

The EXSUM should be faxed to the UNITED STATES ARMY MEDICAL MATERIEL AGENCY (USAMMA) Distribution Operations Center (DOC) at 301-619-4468 (DSN 343-4468). **The DOC must receive an EXSUM before replacement vaccine products will be shipped.**

5. DISPOSAL PROCEDURES: Contact the DOC before destruction of any product issued under the DoD Smallpox Response Plan or DoD Smallpox Preparedness and Vaccination Program Implementation Plan. Smallpox vaccine must be handled as infectious waste. **DO NOT DISCHARGE THIS ITEM INTO A SANITARY SEWER.**

a. Activities will report vaccine inventories on-hand to be destroyed to their respective logistic agencies. The report will include information regarding lot numbers and quantities.

b. Activities must prepare a DA Form 3161, Request for Issue or Turn-In, to document disposal actions and fax a copy within 24 hours after final disposition to the DOC at 301-619-4468 (DSN 343-4468). The disposal code for items 6505-00-903-8173 (Dryvax, full strength), 6505-01-499-9118 (Dryvax, diluted 1:5), or 6505-01-053-2600 (Vaccinia Immune Globulin, intramuscular) is CA01. The disposal code for Cidofovir (Vistide) (NDC #61958-0101-01) is AC01.

c. EXSUM and DA Form 3161 should be sent to:

USAMMA Distribution Operations Center (DOC)
DSN 343-4121/4318/4411/4198/4320/4128
COMM: (301) 619-4121/4318/4411/4198/4320/4128
*FAX: DSN 343-4468 COMM: 301-619-4468
Bonnie.Pereschuk@det.amedd.army.mil

6. METHODS FOR DISPOSAL: Explanations for disposal are detailed in the following MIDI Websites:
http://chppm-www.apgea.army.mil/newmidi/longview.aspx?param=CA01
http://chppm-www.apgea.army.mil/newmidi/longview.aspx?param=AC01

The following procedures are in place in the event the above mentioned disposal methods are not available or immediate disposal is necessary:

a. Contact the DOC and provide information regarding lot numbers and quantities. The DOC will provide further shipping guidance.

b. Remove each vial from its package.

c. Tear or shred the insert and package and dispose of as regular waste.

d. Deface the label on each vial with red permanent marker.

e. The activity will pack the container according to instructions provided and mail the container to DOC.

f. The activity will call the USAMMA, DOC, and provide overnight express-mail tracking number for the container.

7. QUESTIONS OR CONCERNS: Personnel responsible for the disposal and destruction should address all questions or concerns to USAMMA at DSN 343-4307/4309 or (301)-619-4307/4309, FAX x4189.

Changes or updates to this SOP must be brought to the attention of the Distribution Operations Center (DOC), UNITED STATES ARMY MEDICAL MATERIEL AGENCY (USAMMA).

APPENDIX 4 to ANNEX D (LOGISTICS)

Equipment

The U.S. Army Medical Materiel Agency (USAMMA) has been tasked with the responsibility for worldwide distribution of the smallpox vaccine for the Department of Defense (DoD). These products must be maintained within controlled temperature limits while in transit. Exceeding these temperature limits could result in loss of product potency. The following containers are currently in use in support of the Smallpox Vaccination Program (SVP):

The VaxiCool: Is a commercially procured, high-efficiency refrigerator system designed for the local transport and/or temporary storage of smallpox vaccine, vaccinia immune globulin (VIG), and other temperature-sensitive pharmaceuticals.

----Manufacturer: Energy Storage Technologies (EST), Dayton, OH
----Model: VX30PPNR
----NSN: 4110-01-459-3690
----Material: It is comprised of Vacupanel Insulation designed to maintain vaccine at 2° - 8° Celsius
----Payload: 400 vials maximum
----Alternate Power sources: 110 AC (220 w/special cable), car battery, solar panels, and car cigarette lighter
----Batteries: 2-12 volt/12 or 14 Amp gel cell batteries
----Total Purchased: 112
----Price: $3,335 ea

The VaxiCool can maintain temperature after being disconnected from a power source for up to 4 days on internal batteries and 16-24 hours more based on its insulation capabilities.

The VaxiPac: The VaxiPac is a small, commercially procured, high-efficiency insulated container used for transport of the smallpox vaccine, VIG, and other temperature-sensitive pharmaceuticals. It uses a product called VaxiSafe to maintain temperature. The VaxiSafe is composed of a Phase Change Material (PCM) that hardens at 6° Celsius and protects against varying temperatures. The VaxiPac comes with 5 VaxiSafes from the manufacturer.

----Manufacturer: Energy Storage Technologies (EST), Dayton, OH
----NSN: 6515-01-475-8145
----Material: It is comprised of Vacupanel Insulation
----Payload: 1 to 24 vials maximum
----Total Purchased: 300
----Price: $152.62 ea
----VaxiSafe Price: $6.00 ea

The VaxiPac is used for re-distributions for up to 24 hours.

Endurotherm Boxes: A complete packing system designed to ensure the cold chain is not broken. They are available in three different sizes: small, medium, and large. Vaccine is shipped from the National Pharmaceutical Stockpile using Endurotherm boxes, which have gone through various testing protocols. This box can maintain the required temperature for up to 7 days.

-----Manufacturer: Insulated Shipping Container (ISC), Inc., Phoenix, AZ

-----Material: It is comprised of two corrugated layers injected with polyurethane foam within a mold. The end product is a rigid, one piece, three layer laminate container.

-----Payload, weight, and contents prices:

- Small Box: 1-20 vials; packed wt - 15 lbs, contains (6) 24 oz Gel packs, (1) small box insert, packing peanuts, tape, labels, (1) cardboard separator and (1) TempTale = $59.00

- Medium Box: 53-110 vials; packed wt - 25 lbs, contains (9) 24 oz Gel packs, (1) large box insert, packing peanuts, tape, labels, (1) large cardboard separator and (1) TempTale - $64.32

- Large Box: 440 vials; packed wt - 75 lbs, contains (13) 24 oz Gel packs, (4) large box inserts, packing peanuts, tape, labels, (1) large cardboard separator and (1) TempTale = $95.70

ANNEX E – EDUCATION/COMMUNICATIONS PLAN

1. GENERAL. The Department of Defense will begin the Smallpox Vaccination Program (SVP), in accordance with FDA guidelines and consistent with the best practice of medicine.

2. OBJECTIVE. Ensure full understanding and acceptance of the Smallpox Vaccination Program by soldiers, DA civilians, their families, Congress, the American public, and the media.

3. GOALS.

a. Inform all stakeholders that to immunize U.S. forces using smallpox vaccine is the right thing to do to best protect selected personnel at greatest risk, and to preserve certain mission critical capabilities against smallpox.

b. Gain soldier, employee, family member, Congressional, public, and media support for the vaccination of U.S. forces against smallpox.

c. Use this opportunity to inform the American public that biological warfare is a potential threat to our forces.

4. KEY MESSAGES.

a. SMALLPOX WOULD DISRUPT MILITARY MISSIONS, BECAUSE IT IS CONTAGIOUS AND DEADLY.

(1) Disruptive. A smallpox outbreak would significantly affect military readiness.

(2) Contagious. Smallpox is a contagious disease that spreads from one person to another.

(3) Dangerous. Before smallpox was eradicated it killed many millions of people over hundreds of years.

b. SMALLPOX VACCINE PREVENTS SMALLPOX, AND WE WILL USE IT VERY CAREFULLY.

(1) Efficacy. The World Health Organization (WHO) used smallpox vaccine to eradicate natural smallpox from the planet.

(2) Expected Effects and Side Effects. All vaccines cause side effects, but smallpox vaccine causes a unique reaction at the vaccination site.

(3) Care of the Vaccination Site. Smallpox vaccination leaves vaccine virus on the surface of the skin, so you have to be careful not to touch the smallpox vaccination site. You don't want to spread the virus somewhere else.

(4) Side Effects--Serious. Very rarely, smallpox vaccine can cause serious side effects.

(5) Exemptions to Vaccination. Some people should not get smallpox vaccine, except in an outbreak.

(6) Smallpox Vaccine. The Defense Department will use smallpox vaccine licensed by the Food & Drug Administration (FDA).

c. PRESERVING THE HEALTH AND SAFETY OF OUR PEOPLE IS OUR TOP CONCERN.

(1) Healthy troops complete their missions. Vaccines will keep you and your team healthy.

(2) Vaccines have kept troops healthy since the days of George Washington.

(3) Vaccination offers a layer of protection that adds to other measures used to protect certain members of the Armed Forces.

d. SMALLPOX PROTECTION HELPS OUR WAR ON TERRORISM: NEW THREATS REQUIRE NEW MEASURES OF FORCE PROTECTION.

(1) The Defense Department is working with other federal departments to strengthen America's defenses against smallpox.

(2) The government has been preparing for years for the remote possibility of an outbreak of smallpox as an act of terror.

5. CONCERNS.

a. The DoD knows that service members, civilian employees, friends and family, and the American public have concerns about the safety of smallpox vaccination and the lethality of smallpox infection. The following list is an example of concerns from individuals:

(1) The threat: Individuals have questioned the validity and the relevance of the threat (how likely is it that a potential adversary will use these weapons--Is the SVP necessary?)

(2) People have general and specific questions about the safety of the vaccine, especially, the potential side effects, including scarring, encephalitis, and death.

(3) It is important to give correct information to people first. Many times people research information on their own and base decisions and beliefs on what they've heard from others (e.g., internet rumors, urban legends, media) instead of scientific, verifiable facts.

(4) Leaders want good, clear guidance on how to execute the program correctly.

6. CONCEPT OF OPERATION.

a. Education.

(1) Before vaccination, Commanders and supervisors will ensure that vaccine recipients are provided adequate and accurate information on the threat, the vaccine, its safety, its benefits, and site care instructions. Commanders and supervisors will provide all vaccine recipients with a briefing on smallpox and the vaccination program. Your local medical treatment facility maintains stocks of educational trifolds for use. All approved educational material is always available on the web www.smallpox.army.mil.

(2) Commanders are encouraged to provide education for family members of soldiers and civilians receiving smallpox vaccinations. For example, this can be accomplished through family support group meetings at unit level and town hall meetings at installation level.

(3) Healthcare professionals and staff play key roles in this program, both in its execution as well as providing expert advice to soldiers and commanders. They must become familiar with all aspects of smallpox (disease and vaccine).

(4) Commanders should coordinate educational meetings and briefings to ensure full participation by healthcare subject matter experts (SME) and PAO staff.

(5) You can get more information on all aspects of the Smallpox Vaccination Program at the official SVP website, www.smallpox.army.mil. You can also call the SVP toll-free information line at 1-

877-GET-VACC, which is staffed Monday through Friday, 0800-1800 Eastern Standard Time. You can send email inquiries to vaccines@amedd.army.mil.

b. Public Affairs. Public Affairs Offices Army-wide will use informational products developed and designed by OTSG/MEDCOM's Military Vaccine Agency (MILVAX) and approved by DoD to garner internal (Army) and external support of the SVP. All products are available on the DoD Smallpox Vaccination Program Website: www.smallpox.army.mil. DoD provided worldwide Public Affairs Guidance by SECDEF Unclassified Message, 131700Z Dec 02, subject: Public Affairs Guidance (PAG) on the Smallpox Vaccination Program.

c. Responsibilities

(1) Army Commanders:

(a) Oversee coordination and execution of this plan.

(b) Identify spokespersons and points of contact at all levels of command for soldiers, employees, family members, and media.

(c) Ensure vaccinees and family members of vaccinees are briefed on local vaccination plans—coordinate with local hospital commander for medical expert assistance.

(d) Ensure these efforts are coordinated with local medical treatment facility commanders or their representatives.

(e) Ensure these efforts are coordinated with local public affairs officers.

(f) Ensure these efforts are coordinated with local judge advocate or legal advisors.

(2) Army Medical Treatment Facility Commanders:

(a) Coordinate with local commanders the medical aspects of the education/communications plan. Maintain stocks of printed trifolds for local commanders' use in educating their personnel. Trifolds can be printed directly from the web, www.smallpox.army.mil; ordered through OTSG/MEDCOM Military Vaccine Agency, 1-877-GETVACC (staffed Monday through Friday, 0800-1800 Eastern Standard Time); or by sending an email to vaccines@amedd.army.mil.

(b) Ensure medical personnel receive the health care providers briefing (Appendix 4) and have access to the clinical questions and answers (Appendix 6).

(c) Ensure local medical personnel are briefed on local vaccine implementation plans.

(d) Identify a medical subject matter expert to participate in interviews with local and civilian media.

(e) Identify a medical subject matter expert(s) to provide or assist with briefings to soldiers, civilian employees, and family support groups.

(f) Identify a medical subject matter expert or office by name and phone number to be included on all soldier, family member, and civilian educational material.

(3) MACOM Public Affairs Officers. Use questions and answers referenced in Appendix 6 this ANNEX, and DoD issued PAG message to respond to media inquiries. Media inquiries not covered in existing DoD guidance should be referred to Jim Turner at james.turner@osd.mil, (703) 697-5132, DSN 227-5135.

APPENDIX 1 to ANNEX E—(EDUCATION/COMMUNICATIONS PLAN)

TRIFOLD INFORMATIONAL BROCHURE

http://www.smallpox.army.mil/media/pdf/spTrifold.pdf

APPENDIX 2 to ANNEX E—(EDUCATION/COMMUNICATIONS PLAN)

SMALLPOX VACCINE INFORMATION STATEMENT FROM THE CDC

http://www.cdc.gov/nip/publications/VIS/vis-spox.pdf

APPENDIX 3 to ANNEX E (EDUCATION/COMMUNICATION PLAN)

INDIVIDUAL'S BRIEFING

http://www.smallpox.army.mil/media/pdf/spINDBrief.ppt

APPENDIX 4 to ANNEX E (EDUCATION/COMMUNICATIONS PLAN)

HEALTHCARE PROVIDER'S BRIEFING

http://www.smallpox.army.mil/media/pdf/spHCPBrief.ppt

APPENDIX 5 to ANNEX E (EDUCATION/COMMUNICATIONS PLAN)

CDC TRAINING REGARDING NORMAL AND UNUSUAL RESPONSES TO SMALLPOX VACCINATION

http://www.bt.cdc.gov/training/smallpoxvaccine/reactions/normal.html

APPENDIX 6 to ANNEX E (EDUCATION/COMMUNICATIONS PLAN)

QUESTIONS & ANSWERS

http://www.smallpox.army.mil/media/pdf/SPQ&A.pdf

ANNEX F - PERSONNEL

1. SCOPE. This ANNEX applies to all members of the active Army, the Army National Guard (ARNG), and the U.S. Army Reserve (USAR).

2. PURPOSE. To provide the personnel concept of operations and assign responsibility for the implementation of the Army's Smallpox Vaccination Program (SVP).

3. REFERENCES.

a. DoD Directive 6205.3, DoD Immunization Program for Biological Warfare Defense, 26 Nov 93.
- http://www.dtic.mil/whs/directives/corres/pdf/d62053_112693/d62053p.pdf

b. AR 40-562, Immunizations and Chemoprophylaxis, 1 Nov 95.
- http://www.usapa.army.mil/pdffiles/r40_562.pdf

c. AR 220-1, Unit Status Reporting, 15 Nov 01.
- http://www.usapa.army.mil/pdffiles/r220_1.pdf

d. AR 600-8 Military Personnel Management, 1 Oct 89.
- http://www.usapa.army.mil/pdffiles/r600_8.pdf

e. AR 600-8-11, Reassignment, 1 Oct 90.
- http://www.usapa.army.mil/pdffiles/r600_8_11.pdf

f. AR 600-8-101, Personnel Processing (In-and Out-and Mobilization Processing), 1 Mar 97.
- http://www.usapa.army.mil/pdffiles/r600_8_101.pdf

g. AR 600-8-104, Military Personnel Information Management/Records, 27 Apr 92.
- http://www.usapa.army.mil/pdffiles/r600_8_104.pdf

h. AR 600-8-105, Military Orders, 28 Oct 94.
- http://www.usapa.army.mil/pdffiles/r600_8_105.pdf

i. AR 614-6, Permanent Change of Station Policy, 7 Oct 85.
- http://www.usapa.army.mil/pdffiles/r614_6.pdf

j. AR 614-30, Overseas Service, 30 Aug 01.
- http://www.usapa.army.mil/pdffiles/r614_30.pdf

k. DA PAM 600-8, Management and Administration Procedures, 1 Aug 86.
- http://www.usapa.army.mil/pdffiles/p600_8.pdf

l. Under Secretary of Defense (Personnel and Readiness) memorandum, Policy on Administrative Issues Related to the Smallpox Vaccination Program (SVP).
- www.smallpox.army.mil

4. CONCEPT OF OPERATIONS. The Army will implement a phased program to vaccinate members of the Active Army and Reserve Components in accordance with the FDA-approved vaccination schedule and OSD and JCS guidance. This ANNEX delineates responsibilities and establishes personnel policy guidance for the establishment of personnel regulatory and procedural directives.

5. PLANNING ASSUMPTIONS.

a. OTSG administers the Medical Protection System (MEDPROS) automated immunization tracking system to track smallpox immunizations.

b. Interim personnel regulatory changes and policy guidance will be approved and published prior to immunizing the force.

c. Personnel record keeping and movement processing will incorporate administrative redundancies to ensure accurate tracking during movement.

d. The MOS/Medical Retention Board (MMRB) and Medical Evaluation Board (MEB) system will establish assignment limitations in conjunction with medical authority.

e. Commanders will submit requests for exceptions through MACOMs to HQDA, Office of The Surgeon General, Military Vaccine Office, 5109 Leesburg Pike, Falls Church, VA 22041 for approval and coordination with gaining Combatant Command, CJCS and ASD (HA).

6. RESPONSIBILITIES.

a. Deputy Chief of Staff for Personnel, G-1.

(1) Coordinate with U.S. Military Entrance Processing Command (USMEPCOM) all personnel policies pertaining to pre-accession considerations concerning smallpox immunizations.

(2) Observe medical guidelines established by the Surgeon General in ANNEX C when originating personnel vaccination directives.

b. Deputy Chief of Staff for Operations, G-3.

(1) In conjunction with the Deputy Chief of Staff for Personnel, update procedures for readiness reporting which incorporates unit smallpox immunization status.

(2) Establish and/or validate priorities for units and personnel to receive the smallpox vaccine.

c. The Surgeon General.

(1) Advise G-1, G-3, and the Office of the Assistant Secretary of the Army, (Manpower, and Reserve Affairs) on all clinical policy decisions that impact personnel and readiness regulations. Clinical policy must be set prior to incorporation of new personnel policy into existing regulations.

(2) Ensure personnel exhibiting adverse events after smallpox (vaccinia) vaccination are properly profiled. Establish clinical guidelines and establish profile policy for clinicians.

(3) Establish appropriate physician profiles for soldiers experiencing adverse events after smallpox immunizations that preclude further vaccination.

(4) Establish medical policies and implement procedures that delineate populations for which smallpox immunizations are medically contraindicated or not required. Select individuals are exempt from smallpox immunizations and therefore utilization policies must be considered.

d. Commander, Total Army Personnel Command (PERSCOM).

(1) Establish regulatory policy and procedural requirements to ensure smallpox immunization status is properly documented in orders prior to movement of personnel.

(2) Establish in- and out-processing controls that cause soldiers on assignment instructions to designated areas to complete smallpox immunizations prior to permanent change of station.

(3) Incorporate smallpox immunization requirements and documentation into all Soldier Readiness Processing (SRP) regulatory guidance.

e. Chief, National Guard Bureau (NGB).

(1) Advise G-1 regarding the impact of the SVP on National Guard personnel and units.

(2) Develop and coordinate National Guard smallpox immunization policy for State Area Commands and the Air National Guard.

(3) Develop policy and procedures for documenting smallpox vaccination response and immunization adverse event medical profiles in personnel and medical records so they can be used for readiness and mobilization processing.

(4) Establish a business process to monitor the incidents of adverse event that occur after the soldier has been released from military control (i.e. annual training, BCT, AIT).

f. Chief, Army Reserves (CAR).

(1) Advise G-1 regarding the impact of the SVP on USAR personnel and units.

(2) Develop and coordinate USAR smallpox immunization policy for major commands, and the U.S. Army Reserve Personnel Command (AR-PERSCOM).

(3) Develop policy and procedures for documenting smallpox vaccination response and immunization adverse event medical profiles in personnel and medical records so they can be used for readiness and mobilization processing.

(4) Establish a business process to monitor the incidents of adverse event that occur after the soldier has been released from military control (i.e. after annual training, BCT, AIT).

ANNEX G - ARMY NATIONAL GUARD

1. PURPOSE. Provide the Army National Guard (ARNG) concept of operations and planning guidance to the States and Territories for implementing the Smallpox Vaccination Program (SVP).

2. SCOPE. This ANNEX applies to all members of the Army National Guard.

3. Planning assumptions:

a. ARNG soldiers participating in designated areas such as homeland security missions and/or units likely to deploy in support of specific theater of operation where the threat of smallpox is likely, may be vaccinated.

b. All other ARNG soldiers will be placed into the appropriate Priority Category upon notification/selection for selection in an operation located within a designated area.

c. The DA Plan and this ANNEX allow maximum flexibility to the states to use internal and external resources.

d. The Weapons of Mass Destruction (WMD) - Civil Support Teams (CST) will respond to terrorist threats that will require early immunizations of CST team members (Stage 1a).

e. The immunization status of each ARNG member will be tracked by the State Area Command (STARC) using the DA approved tracking system at ANNEX J (MEDPROS). The system will interface and update DEERS.

f. The smallpox vaccine will continue to be the requirement throughout the period of implementation unless notified of an FDA-approved change.

g. DoD will fund additional expenses associated with administration of this program. These costs include, but are not limited to the following: contracts, ancillary supplies, shipping, man-days/per diem/travel for additional training assemblies required for soldiers administering the program and for those receiving the injections, and may qualify for incapacitation pay for treatment of those having adverse reactions.

h. The ARNG will have access to any contracted resources and funding to contract resources to administer the vaccine.

4. RESPONSIBILITIES.

a. G1 Chief, Human Resources Division.

(1) Develop and coordinate the SVP for ARNG.

(2) Ensure the procurement of vaccine and ancillary supplies required to implement the Smallpox Vaccination Program within the National Guard.

b. The ARNG Program Analysis, and Evaluation Division (NGB-ARA). Develop requirements for submission to appropriate Program Evaluation Group (PEG) for the purpose of competing in the Program Objective Memorandum (POM) process.

c. The ARNG Information Management Division (NGB-AIS). Ensure adequate communication support for tracking mechanisms.

d. The ARNG Policy and Communications Office (NGB-ARZ-PC). Develop a public affairs plan in coordination with DoD, DA, and NGB-PA.

e. The ARNG Surgeon's Office (NGB-ARS). Provide related medical policy and guidance.

f. State TAG will:

(1) Ensure ARNG personnel are immunized against smallpox IAW Army guidance.

(2) Develop State plan for implementation of SVP.

(3) Track unit immunization status and provide reports as required.

g. State Area Command (STARC) Medical Detachment will coordinate:

(1) Immunizations in support of state plan.

(2) Annotation of immunizations, including smallpox vaccination response, in the Health Record and the Army's automated immunization tracking system (MEDPROS) IAW ANNEX J.

(3) Commanders' requirements for patient education support.

(4) Adverse event reporting.

(5) Requisition required vaccine and ancillary supplies IAW overall Army plan.

5. CONCEPT OF OPERATIONS.

a. Implementation. The ARNG will implement the SVP IAW priorities established by the Office of the Secretary of Defense (OSD) and the Joint Chiefs of Staff. Reserve Component personnel shall be in a duty status when receiving a DoD directed immunization. Additional guidance on ARNG Program Implementation will be published for the states as an "All States Log Memorandum."

b. Method of Immunization. Implementation of the immunization plan will be based on the state plan to be administered by the STARC Medical Detachment. Resources to vaccinate personnel/units may be used as appropriately coordinated, to include organic medical assets, active component facilities, public health service, or VA medical assets, or private sector contractor. The plan will include processes to evaluate smallpox vaccination responses.

c. Record Keeping. Immunization will be noted in Public Health Service Form PHS 731 (International Certificate of Vaccinations), the Soldier's Health Record, and MEDPROS.

d. Tracking System. Immunizations will be entered into MEDPROS IAW ANNEX J. In anticipation of mass immunizations and mandatory automated tracking, the STARC will identify all personnel requiring access to the automated tracking system, ensure they meet access requirements, and determine the data access level.

e. Logistics. On execution, USP&FO will be responsible for initiating requests for vaccine IAW ANNEX D. USAMMA will direct the distribution of the vaccine and ancillary supplies, as applicable, to the sites designated in the request.

f. Adverse Events. Commanders will establish a mechanism to monitor incidents of adverse event, to include those that occur after the soldier has been released from military control, IAW ANNEX C. National Guard members who experience adverse events and are seeking health services outside of a Military Treatment Facility must contact the Military Medical Support Office (MMSO) at 1-888-647-6676 for guidance.

g. PAO Information. Commanders at all levels will support an aggressive command information program in support of the SVP IAW ANNEX E.

h. Command Responsibility. The execution of the SVP is a command responsibility. The Adjutants General and Commanders at all levels will coordinate with supporting medical activities to ensure that soldiers receive required immunizations.

6. POC: ARNG- Health Care Operations Officer DSN 327-9066 or comm. 703-607-9066.

ANNEX H - U.S. ARMY RESERVE

1. PURPOSE: This ANNEX defines the application of the concept of operations from the basic Smallpox Vaccination Program (SVP) Plan to the U.S. Army Reserve (USAR).

2. SCOPE: This ANNEX applies to all members of the USAR.

3. CONCEPT OF OPERATIONS:

a. Upon order of HQDA, USAR personnel will begin implementation of the SVP. The following USAR organizations will establish policies and procedures governing administration of the SVP for their designated soldier populations per Part 3.a. of the basic plan and ANNEX F.

(1) USARC for CONUS and Puerto Rico based Troop Program Unit (TPU) soldiers under its command and control.

(2) United States Army Europe (USAREUR) and 7th Army Reserve Command (7th ARCOM) for soldiers in their Area of Responsibility (AOR).

(3) United States Army Pacific (USARPAC) and 9th Regional Support Command (9th RSC) for soldiers in their AOR.

(4) US Army Special Operations Command (USASOC) for assigned USAR TPU and Individual Mobilization Augmentee (IMA) soldiers.

(5) U.S. Army Reserve Personnel Command (AR-PERSCOM) for IMA (other than USASOC) and Individual Ready Reserve (IRR) soldiers.

b. Commanders will schedule immunizations in compliance with the FDA vaccination protocol while avoiding training disruptions.

(1) Planning factors for scheduling immunizations should include training and mobilization requirements, allowing sufficient time to administer the immunization and record the effectiveness of the inoculation, and administration of other immunizations IAW sound medical judgment. There is no need to defer this or other immunization until mobilization unless medically contraindicated.

(2) Maximum coordination with other active, USAR, and ARNG commands at the regional level – i.e. Regional Support Commands (RSCs), State Area Command (STARC), and Regional Medical Commands (RMCs) – is encouraged to produce economies of scale and minimize disruption to training.

(3) Reserve component personnel must be in a duty status when receiving a DoD-directed immunization.

c. Command responsibility. The execution of the SVP is a command responsibility. USAR Commanders at all levels will coordinate with supporting activities to ensure that soldiers receive the required immunization per the schedule outlined in the basic plan.

d. Method of immunization.

(1) The primary method of delivery for smallpox vaccine will be by contract provider via the Federal Strategic Health Alliance (FEDS_HEAL) program. FEDS_HEAL providers include the Department of Health and Human Services Division of Federal Occupational Health (FOH), Department of Veterans Affairs (VA) medical assets, and subcontracted civilian providers. Other resources may be used as appropriately coordinated, to include organic medical assets and active component facilities of all Services.

(2) Department of Defense and Federal facilities available for USAR execution of the SVP. Immunizations should be available at times and places other than at TPU locations during drill weekends or during Annual Training. The United States Army Medical Command (MEDCOM) will assist the USAR in determining the optimal location and method for completing smallpox vaccination. Every effort will be made to ensure that smallpox vaccine is available in the selected DoD, other Federal, or contract facilities to ensure that soldiers can obtain immunizations on the day that is required for their individual immunization schedule. The plan will include processes to evaluate smallpox vaccination responses.

e. Contract Funding. Upon request, OCAR Program Analysis and Evaluation (PAE) Division will provide input to MEDCOM Resource Management concerning development of any USAR Statement of Work (SOW) for use by Federal Agencies or civilian contractors.

f. Prioritization of Troop Populations. The USARC, AR-PERSCOM, 7th ARCOM, 9th RSC, and USASOC will prioritize troop populations to receive immunization IAW HQDA prioritization guidance. Priorities will be as follows:

(1) Forces assigned or rotating to higher threat areas as delineated.

(2) Selected Reserve (SELRES) forces.

(3) Remainder of Total Force and accessions.

g. Record keeping. Annotation of immunizations to medical records (MEDPROS, SF 601, and PHS Form 731) per the basic plan will be accomplished by the medical treatment facility or contractor administering the vaccination. The plan will include processes to evaluate smallpox vaccination responses.

h. Tracking System. Immunizations will be entered into the DA-designated automated immunization tracking system (MEDPROS) IAW ANNEX J and reported IAW ANNEX F. Commanders, USARC, AR-PERSCOM, 7th ARCOM, 9th RSC, and USASOC will develop procedures to identify all personnel requiring access to the automated tracking system, ensure they meet access requirements, and determine data access level IAW ANNEX J.

i. Logistics. The U.S. Army Medical Material Agency (USAMMA) will direct the distribution of the vaccine to FEDS_HEAL providers, USAR units and, when applicable, supporting Installation Medical Supply Activities (IMSAs) per ANNEX D. IMSAs will coordinate directly with the designated medical facilities or providers for distribution of the vaccine to the immunization sites. Ancillary supplies will be the responsibility of the immunizing entity per the basic plan.

j. Adverse Events.

(1) Commanders will establish a mechanism to monitor the incidents of adverse events that occur after the soldier has been released from military control. See ANNEX C, Part 8.b., for adverse event reporting requirements.

(2) Army Reserve members or family members who experience adverse events and are seeking health services outside of a Military Treatment Facility must contact the Military Medical Support Office (MMSO) at 1-888-647-6676 for guidance.

(3) Commanders will ensure a line of duty determination is completed for all adverse events, regardless of whether or not medical care is sought or the source of such care.

k. Public Affairs Office (PAO) Information. Commanders at all levels will support an aggressive command information program in support of the SVP. Commanders must use and will not deviate from the PAO information provided by HQDA. This program will include:

(1) Threat briefing.

(2) SVP specific information as outlined in the basic plan and ANNEX E.

l. Resource Management. The Office of the Chief, Army Reserve (OCAR), PAE Division, will provide MEDCOM with the USAR SVP cost estimates for the development of Program Objective Memorandum (POM) submission to the DHP. This funding estimate will provide for immunization services and for future SVP activities, defined in the basic plan as determined by DoD and HQDA.

4. RESPONSIBILITIES.

a. OCAR will provide appropriate USAR immunization prioritization guidance (for identification of USAR units and personnel to be immunized) through command channels to USARC, AR-PERSCOM, 7th ARCOM, 9th RSC, and USASOC.

b. USARC will develop an implementation plan in coordination with MEDCOM.

c. AR-PERSCOM will develop an implementation plan in coordination with MEDCOM.

d. 7th ARCOM will develop an implementation plan in coordination with European Regional Medical Command and MEDCOM.

e. 9th RSC will develop an implementation plan in coordination with Pacific Regional Medical Command, Western Regional Medical Command, 18^{th} Medical Command, and MEDCOM.

f. USASOC will develop an implementation plan for assigned USAR soldiers in coordination with MEDCOM.

ANNEX I - DEPARTMENT OF THE ARMY CIVILIANS AND DOD CONTRACTORS

1. GENERAL.

a. Smallpox vaccination will be mandatory for DA civilians in designated "Emergency Essential" (E-E) positons and civilian contractor personnel carrying out "mission essential" (ME) services, who are eligible for vaccination IAW paragraph 3.a., this basic plan. For civilian personnel in category 1.f.(5), vaccination shall not be mandatory; these personnel should be offered and encouraged to receive FDA-licensed smallpox vaccine, unless medically exempted. For vaccinations of civilian personnel, ensure all bargaining obligations are fulfilled IAW Federal Services Labor Management Relations Statute prior to implementation.

b. Commanders may also identify and recommend other cohorts of personnel for vaccination against smallpox though the Executive Agent to the ASD(HA), if they deem their occupations may place them at higher risk for exposure to smallpox. Send requests to HQDA, Office of The Surgeon General, Military Vaccine Agency, 5109 Leesburg Pike, Falls Church, VA 22041 for coordination with and approval by HQDA, CJCS and ASD(HA).

c. DoD Directive 6205.3, DoD Immunization Program for Biological Warfare Defense, dated 26 Nov 93, applies to essential DoD civilian personnel, and personnel of other Federal Departments, when assigned as part of the U.S. Armed Forces. DoD Directive 1404.10, "Emergency-Essential (EE) DoD U.S. Civilian Employees," addresses policy to ensure the continued performance of civilians that have been designated EE before crisis situations; it also addresses civilians who have not been previously designated EE, but whose continued performance is deemed essential to support combat-essential systems. DoD Instruction 3020.37, "Continuation of Essential DoD Contractor Services During Crises," dated 6 Nov 90, with Change 1 dated 26 Jan 96, states that employees designated as mission essential must be identified as such in the contract statement of work (SOW). DoD civilians and contractors are subject to the same vaccination requirements as active-duty personnel upon deployment. For contract personnel the designation as "Emergency Essential" would appear in the contract.

d. Command-directed smallpox vaccinations are administered without charge to civilian employees.

e. EE civilians and ME contractors will be vaccinated IAW with MACOM guidelines, in most cases going to the nearest MTF for vaccination.

2. CONSENT FOR IMMUNIZATION.

a. Civilian employee immunization is given with consent. All employees will be encouraged to accept smallpox vaccination when offered. However, in instances where smallpox vaccination for civilians is mandatory, vaccination will be a condition of employment.

b. The effect on a Department of the Army employee who refuses immunization when indicated will be determined by the appropriate supervisor or commander in conjunction with representatives of the Civilian Personnel Office and the servicing legal office. Army policy requires that management first consider taking a non-adverse action, such as a reassignment to a non-EE position; identification of an alternate employee who is willing to be immunized and serve as an EE; curtailment of tour, etc. If none of these are possible, the EE could be subject to adverse actions, up to and including, removal from the federal service for failure to meet a condition of employment. Refusal of smallpox immunization should be documented in appropriate personnel and health records.

3. DOCUMENTATION.

a. Education. Supervisors will be responsible for ensuring that civilian employees are adequately trained and aware of the health risk of smallpox as a biological weapon, and document that this training was received. Supervisors are responsible for ensuring compliance with the education requirements for vaccine recipients detailed in Annex E, paragraph 6.a.(1).

b. Refusal of immunization must be documented as indicated in Part 2. b. in this ANNEX.

c. Documentation of immunization.

(1) All smallpox immunizations will be recorded in the appropriate health record and on a PHS Form 731. Written entries will contain the data elements described in ANNEX C. Civilian smallpox immunizations will also be recorded in the Army's automated immunization tracking system, MEDPROS, IAW ANNEX J.

(2) Serious adverse events to immunization will be recorded in the occupational health record, and reported through the Army Medical Surveillance System IAW ANNEX C.

ANNEX J - IMMUNIZATION TRACKING SYSTEM

1. PURPOSE. To provide the concept of operations for tracking smallpox vaccinations using an automated Immunization Tracking System (ITS).

2. GENERAL INFORMATION.

a. The Army will vaccinate forces against smallpox IAW the FDA immunization protocol and DoD policy. The smallpox vaccine is administered in one dose according to FDA protocol.

b. Soldiers and civilians who receive smallpox vaccine may change duty stations, be deployed and/or be on leave. An automated ITS provides visibility to these personnel and their commanders or supervisors of the individual's immunization status, and ensures that their immunization history will be annotated in their permanent electronic data record.

3. CONCEPT OF OPERATIONS.

a. The Army uses the Medical Protection System (MEDPROS) as its automated ITS to track smallpox vaccinations. MEDPROS is a subset of the Medical Operational Data System (MODS). The MODS system resides on a mainframe computer system at the Pentagon. MEDPROS is a modern, easy to use, web-based tracking system, accessed from the Internet at http://www.mods.army.mil/.

(1) Users may request a LOGON ID directly from the website or may call the MODS help desk at the numbers in paragraph 6, this ANNEX, for assistance. The MODS help-desk is manned 24 hours a day to assist you with MEDPROS-related questions.

(2) Required ITS data elements include: patient name, SSN, date of immunization, name of vaccine, lot number, manufacturer, and route of administration, name of provider, documented take recorded, and consent form (if required).

(3) All smallpox immunizations will be recorded in MEDPROS within 24 hours of the immunization event.

(4) Immunizations will be posted in the patient's paper health record IAW ANNEX C.

(5) Vaccination response will be entered in the "REACT" or "REACTION" field after the vaccination site is evaluated 6 to 8 days after vaccination. The immunization record will be annotated with "MAJOR" for major reaction or "EQUIV" for an equivocal reaction, using the definitions adopted by the World Health Organization and the Centers for Disease Control and Prevention.

b. MEDPROS Training. Classroom training is available at the MODS contractor main location in CONUS in northern Virginia. Additionally, civilian MODS contractors will be available on a limited basis for off-site training. The MODS contractor and the OTSG/MEDCOM Military Vaccine Agency (MILVAX) also have regional analysts who are available on a limited basis to provide "train the trainer" courses across MEDCOM and the Army. To arrange MEDPROS training, contact the MODS help desk or call the MILVAX senior program analyst at the numbers in paragraph 6, this ANNEX.

(1) Classes are 12-16 hours long (depending on level of training) and include orientation, demonstration, and practical exercises. For off-site training, a classroom with computer terminals is required with no more than two students per terminal. Terminals must be able to access a Local Area Network (LAN), a Wide Area Network (WAN), or have modems for Terminal Server Access Connection System (TSACS)/internet access. MEDCOM developed the Enhanced Remote Immunization Data Entry System (RIDES-E) for units that do not have LAN, WAN or Internet access. RIDES-E requires the use of a lap top computer with a CD reader. You can contact the MODS help desk for information on implementing this system.

(2) Those personnel who actually enter immunization data (into MEDPROS) at point of service of immunizations should be targeted for training; i.e. personnel at immunization clinics, Troop Medical Clinics and all levels of Command through battalion level who are responsible to the Commander to enforce vaccination schedules and keep the Commander informed (Battalion/ Brigade S1s, PSNCOs, etc). Ideally, personnel/units who are scheduled for deployment to designated areas should get MEDPROS training BEFORE they deploy, as training in CONUS is not as problematic.

c. Other Services' military members, Department of Defense Civilian Employees and DoD Contractors may receive their vaccinations at Army MTFs IAW this plan and will be tracked using MEDPROS. Immunizations will be recorded in MEDPROS for non-military Army personnel by adding their names utilizing the task force function. The MEDPROS system will report smallpox immunization data to DEERS. Other services will gain visibility of their members vaccinated in Army facilities from the DEERS reports. MEDPROS will also read data from DEERS and record confirmation of soldiers receiving smallpox immunizations from another service (MEDPROS queries DEERS on a monthly basis for this purpose). DEERS is the central repository for the smallpox immunization data and will provide reports as required.

4. RESPONSIBILITIES.

a. U.S. Army Medical Command.

(1) Field MEDPROS and RIDES-E and train users.

(2) Provide oversight for Immunization Tracking System.

(3) Maintain quality control of the immunization tracking process performing checks for accuracy as necessary and ensuring that all smallpox immunizations are recorded within the MEDPROS system within 24 hours of the immunization event.

b. 18th Medical Command.

(1) Provide oversight for Immunization Tracking Program on the Korean Peninsula.

(2) Record all smallpox immunizations within the MEDPROS system within 24 hours of the immunization event.

(3) Maintain quality control of the immunization tracking process performing checks for accuracy as necessary. Report discrepancies to HQ MEDCOM.

5. REPORTING: The following reports will be available from MEDPROS:

a. Individual immunization status report by SSN.

b. List of personnel by UIC that are due for a specific immunization by type and series.

c. Percent of personnel by UIC who are due a specific immunization by type and series.

d. Percent of personnel by UIC who have received the immunization.

e. List of personnel by UIC who have received the immunization.

6. COORDINATING INSTRUCTIONS. USAMEDCOM DCSOPS will serve as the single point of contact for questions and/or problems experienced with MEDPROS. POCs for MEDPROS are:

a. USAMEDCOM DCSOPS: Medical Readiness and Training Branch, Operations Division
Comm: (210) 221-7124
DSN: 471-7124
FAX: 471-7061

b. MODS Help Desk
ASM Research, MODS Project Office:
Comm: (703) 681-4976/5008 or 1-888-849-4341
DSN: 761-4976/5008
International toll-free, Korea: 0-130-81-9261
International toll-free, Germany: 00798-14-8002803

c. Military Vaccine Agency, Senior Program Analyst
MEDPROS training coordinator.
Comm: 1-703-681-1692 or 1-877-GETVACC



世界衛生大會 決議 قرار جمعية الصحة العالمية
RESOLUTION OF THE WORLD HEALTH ASSEMBLY
RÉSOLUTION DE L'ASSEMBLÉE MONDIALE DE LA SANTÉ
РЕЗОЛЮЦИЯ ВСЕМИРНОЙ АССАМБЛЕИ ЗДРАВООХРАНЕНИЯ
RESOLUCION DE LA ASAMBLEA MUNDIAL DE LA SALUD

СОРОК ДЕВЯТАЯ ВСЕМИРНАЯ АССАМБЛЕЯ ЗДРАВООХРАНЕНИЯ **WHA49.10**

Пункт 18.1 повестки дня **25 мая 1996 года**

Ликвидация оспы - уничтожение запасов вируса натуральной оспы

Сорок девятая Всемирная Ассамблея здравоохранения,

Отмечая, что 8 мая 1980 года Тридцать третья Всемирная Ассамблея здравоохранения в резолюции WHA33.3 провозгласила глобальную ликвидацию оспы;

Отмечая далее, что в резолюции WHA33.4 были одобрены рекомендации на период после ликвидации, в которых указывалось, что оставшиеся запасы вируса натуральной оспы должны храниться только в ограниченном количестве мест и, что запасы вируса натуральной оспы с тех пор были сокращены и ограничены сотрудничающим центром ВОЗ по натуральной оспе и другие поксвирусные инфекции, выявленные в Центрах по контролю и профилактике заболеваний, Атланта, Джорджия, США, и Российском государственном научно-исследовательском центре вирусологии и биотехнологии, Кольцово, Новосибирская область, Российская Федерация;

Признавая, что информация о последовательности в геноме нескольких штаммов вируса натуральной оспы и клонированные фрагменты ДНК генома вируса натуральной оспы позволяют решать научные вопросы о свойствах вирусных генов и белков, а также любые проблемы с диагностикой предполагаемой оспы, и что утечка вируса натуральной оспы из лабораторий позволит быть серьезным риском, поскольку все большая доля населения не имеет иммунитета к натуральной оспе,

РЕКОМЕНДУЕМ, оставшиеся запасы вируса натуральной оспы, включая все вирусы натуральной оспы, вирусную геномную ДНК, клинические образцы и другие материалы, содержащие инфекционный вирус натуральной оспы, должны быть уничтожены до 30 июня 1999 года, в соответствии решением, предложенным 31 декабря 1993 года специальным комитетом по ортопоксвирусным инфекциям, на Ассамблеи здравоохранения - мораторий на пять с половиной лет.

Шестое пленарное заседание, 25 мая 1996 года
A49/VR76